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Meeting on Fresh Citrus Juice

Transcript of Proceedings

Volume I: Wednesday, December 8, 1999
Volume II: Thursday, December 9, 1999
Volume III: Friday, December 10, 1999

Volume II
Thursday, December 9, 1999

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Jacque Knight, Advisory Committee Specialist

ALSO PRESENT

Dr. Larry Beuchat, University of Georgia

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AGENDA ITEM

PROCEEDINGS

MS. OLIVER: Once again, my name is Janice Oliver. I'm Deputy Director of FDA's Center for Food Safety and Applied Nutrition, and I'm going to be chairing the meeting today. Dr. Wachsmuth is unable to be with us again and sends her regrets. Dr. Karen Hulebak may be here later today, but Dr. Engeljohn is here in her absence this morning from USDA.

I want to take care of a few housekeeping things and some other things first, and then we'll go into a follow-up to yesterday's meeting, if we could.

First, I'd like to introduce Dr. Susan Alpert, who is FDA's new Director--Susan, if you'd stand--FDA's new Director of Food Safety at the Center for Food Safety and Applied Nutrition. She's taking--you know Morrie Potter, and Morrie Potter was previously Director of the Food Safety Initiative, and that is part of Dr. Alpert's job right now. She was formerly the Director of the Office of Device

Evaluation at our Center for Devices and Radiological Health. Prior to that, she was a medical officer in the Division of Anti-Infective Drug Products at our Center for Drug Evaluation and Research. She also served as the supervisor for anti-infective and dermatological drug products, so she has a broad background there. But her background, she has a degree in biology and she has a Ph.D. in microbiology, so she has a strong background in micro. She has an M.D. and is a pediatrician, and she completed her training also in pediatric infectious diseases, so that she has a broad background in those areas, and Dr. Alpert will be here with us today and most of tomorrow also. So she wants to meet some of you and talk with you and I'm sure will be interacting with you in the future. So, welcome.

The next thing I'd like to do for the record, since this is being transcribed, is once again have the members and our guest expert introduce themselves. And first I'd start with Dr. Beuchat, who is our guest expert.

DR. BEUCHAT: Larry Beuchat, University of Georgia.

MR. RUSSELL: Leon Russell, Texas A&M University.

MR. SVEUM: Bill Sveum, Campbell's Soup Company.

DR. DONNELLY: Cathy Donnelly, University of Vermont.

MR. JAHNCKE: Mike Jahncke, Virginia Tech.

DR. KOBAYASHI: John Kobayashi, Washington State Health Department.

DR. O'BRIEN: Alison O'Brien, Uniformed Services University.

DR. GROVES: Mike Groves, LSU.

MR. DICKSON: Jim Dickson, Iowa State University.

DR. SPERBER: Bill Sperber, Cargill.

DR. BUCHANAN: Bob Buchanan, FDA.

DR. SWAMINATHAN: Bala Swaminathan, CDC.

DR. MORALES: Roberta Morales, Research Triangle Institute.

MR. ANDERS: Jim Anders, North Dakota Health Department.

MR. EKLUND: Mel Eklund, Mel Eklund Associates, from the peaceful city of Seattle.

[Laughter.]

LTC SEVERIN: Scott Severin, DOD.

DR. LIANG: Art Liang, CDC.

MS. JACKSON: LeeAnne Jackson, FDA, CFSAN.

DR. TROXELL: Terry Troxell, FDA, CFSAN.

DR. ENGELJOHN: Dan Engeljohn, USDA, Food Safety and Inspection Service.

DR. DOYLE: Mike Doyle, University of Georgia.

DR. DOORES: Stephanie Doores, Penn State University.

MR. ROBACH: Mike Robach, Conti Group Companies.

MS. NAGLE: Nancy Nagle, Nagle Resources.

DR. KVENBERG: John Kvenberg, FDA.

MR. ACHESON: David Acheson, New England Medical Center and Tufts University.

DR. NEILL: Peggy Neill, Brown University, in the city for the little TV show, Providence.

MR. SEWARD: Skip Seward, McDonald's.

DR. BERNARD: Dane Bernard, National Food Processors Association.

DR. LONG: Earl Long, CDC.

DR. TOMPKIN: Bruce Tompkin, Armour Swift-Eckrich.

MS. OLIVER: Good. Thank you very much.

The next thing I'd like to do is, an agenda, a draft agenda was passed out for today, and what I'd like to see is if the Committee agrees with the agenda, has any questions about the plans for the day.

DR. SPERBER: I notice there's no time on the agenda. Do you have any rough idea of timing for today?

MS. OLIVER: The draft agenda we had before was to possibly adjourn around 2:30. What I'd like to do is see how the meeting goes, and depending on how the deliberations and discussion goes in the morning, we may adjourn earlier or we may adjourn a little later.

We're planning on having a break an hour and a half to two hours into the morning. I will play it by ear so that depending if we're in the middle of a discussion on one point, we can break a little earlier or later. Is that helpful?

DR. SPERBER: Sure.

DR. TOMPKIN: I would like to know, are we going to focus on fresh juice today, or are we going to be talking about juice in the more broader sense? I'd like to know where we're going.

MS. OLIVER: Okay. I'm going to go over that when we focus on what the day's discussions will be. Okay?

Anything else?

[No response.]

MS. OLIVER: Okay. With that, what I'd like, is there a motion to adopt the agenda?

DR. DONNELLY: So moved.

MS. OLIVER: A second?

DR. NEILL: Second.

MS. OLIVER: Okay. Fine. That's done.

Now, the next thing I'd like to do is get--look at--ask everybody, you have a copy of the draft minutes that were supplied you from the meeting from September 21st to 24th. They're included as tab B in your notebooks. I'd ask, is there any discussion at all on the minutes?

[No response.]

MS. OLIVER: No discussion on the minutes. Do I hear a motion to adopt?

DR. GROVES: So moved.

MS. OLIVER: Second?

MS. NAGLE: Second.

MS. OLIVER: Does everybody agree?

[No response.]

MS. OLIVER: Okay. Now, let's go and talk now about the focus of today's meeting, and I think that's where everybody is concerned about. But what I'd like to do first is I'd like to clarify some things that came up yesterday, either questions that came to me from the Committee or from members that were presented or the audience or questions--some things that I'd like to clarify based on comments that were made yesterday, clarify for the Committee.

The first has to do with an understanding of the process that FDA is undergoing and where this fits into our process.

Dr. Troxell told you yesterday that we had proposed a juice HACCP rule which you're all familiar with. We're in the process of rulemaking. The comment period had closed for the juice HACCP period. In reviewing the

comments that came in, there were several comments that dealt with the possibility of infiltration of pathogens into citrus. There were other comments, as he said, that dealt with where does the 5-log start, and there were questions of interpretation.

In response to that, FDA did some research. That research was presented here, and you heard comments on the research and on research that other people did yesterday. What we're doing is we're asking the Committee for input on specific questions relating to the infiltration or internalization of pathogens into citrus juice, and we're also asking questions that deal with where does the 5-log start. And we're dealing with fresh juice.

Now, what we will do is, following this meeting, we're transcribing the meeting, the transcript will be turned around--within about 24 hours we'll get it, and we will send it to our docket. It will be a part of our--the comments in the docket, and it will be placed on the Web. That should happen fairly shortly, so that the transcript and the results of this meeting will be used in the evaluation as part of our rulemaking process, and we'll take the advice and look at this as advice from the Advisory Committee.

What we will be doing and what the juice HACCP rule will or will not look like or finalization or comments to the proposal will not be done at this meeting. Some people had misinterpreted that, that the finalization will happen here.

The comment period was reopened on November 23rd. The comment period will remain open until January 24th. Therefore, individuals have a chance to comment on what has already been placed in the docket, which includes the research that we presented yesterday, and that is a part of your booklet from FDA. Individuals will also then have the opportunity to comment on the deliberations from this Committee as this will be made a part of the official record. So just to clear that up and focus that part.

There were a number of other questions that arose yesterday on outbreaks. The focus of this meeting is not on outbreaks but on the questions we have, but there were some questions that arose that if we had the results of certain things or you needed certain information, it would be helpful to have certain information in order for you to respond to us.

The first thing is Laurie Girand's slides yesterday did not appear and did not work on the overhead. They were made and distributed to you yesterday afternoon.

Dr. Ismail also had slides dealing with outbreaks. He provided a copy of that this morning. We are copying that, and that will be given to you this morning. But if you have questions, that will be given.

We have also, FDA has also provided a summary of outbreaks to you this morning. LeeAnne Jackson can answer any comments that you might have on that if you have some later.

There were also comments that were made yesterday on the causes of various outbreaks, and there was some confusion in my listening to the comments and the presentations and the questions. There could be some confusion that the current recall that is underway by Sun Orchard is associated with outbreaks. So let me just go

through a few things.

There was an outbreak associated with Sun Orchard. That was earlier this year, and there was a recall associated with that. There currently is a recall by Sun Orchard. That recall was not associated with an outbreak that we know of. The recall was based on Sun Orchard's sampling, their finding of Salmonella in the product, so that Sun Orchard did the sampling and entered into a voluntary recall.

There are a number of questions that have been asked about, and I think Dr. Tompkin made a comment yesterday that knowing the cause of the various outbreaks would be very beneficial for this Committee in your deliberations.

Let me go through a few things and tell you what I know and what I don't know, and let me start with the most recent.

The recall by Sun Orchard of Salmonella in orange juice that is currently ongoing is currently under investigation, still under investigation by the firm, by the states, and by FDA. We do not know the cause at this time, and it would be purely speculative to go into anything. And since it also is under active investigation, it is not something that we would be able to further discuss.

The previous outbreak that--there were a number of comments made by different people saying or intimating that the cause was definitively found for the previous outbreak on Sun Orchard. We, FDA, did not find or do not know the definitive cause for the previous outbreak on Sun Orchard. There were samples that were taken. We have positive samples for Salmonella. We also had a positive sample that showed multiple serotypes of Salmonella from a tanker that was taken that was incoming into the country to go to Sun Orchard.

There was never a final determination as to that. There were comments made yesterday about ice, and the sample that FDA took of the ice did not come out as a positive for Salmonella. And I'm looking at John to verify that. It was negative. So I think I just want to put that on the record so that you have some of these facts in doing the deliberations. So the definitive cause was not known.

I think to try and speculate all of that is not worth talking about a whole lot of discussion when it's not known, but those are the facts that go with that.

The outbreak in Florida, I would leave that to someone from Florida if they wanted to add. Dr. Parish, I know, is very much involved. I do not know if he happened to be--yes, he happens to be here this morning. If you wanted to say what the cause of the outbreak in Florida was?

DR. PARISH: There was never--

MS. OLIVER: Could you come to--you can use this mike right here.

DR. PARISH: Mickey Parish, University of Florida.

The so-called smoking bullet was never found. Specifically, we did not find the exact serotype that caused the illnesses in any part of the plant. However, Salmonella strains were isolated from unopen bottles of juice from the plant. Salmonella strains were found in amphibians that were in close proximity to some of the equipment and in close proximity to the plant.

In one case, there was a Salmonella Hartford which

caused most of the illnesses, a Salmonella Hartford found on an amphibian outside the plant. However, it was not the exact same serotype.

MS. OLIVER: Thank you.

We can come back and ask questions, but I just wanted to clarify some things from yesterday.

Another discussion that was related throughout the day dealt with the Florida program, sometimes calling it a HACCP program, sometimes not calling it a HACCP program, saying that it is a mandatory program, some saying that there were requirements and some confusion.

What I'd like to do is to--Dr. Troxell talked to Dr. Martha Roberts last evening to clarify some of that, and then somebody from the State of Florida can add to that to clarify any that you have so that you know what the program actually is. And we can reference what has been supplied in your book so there's a clarification there.

DR. TROXELL: Thank you. Yes, Martha Roberts indicated it is a not a HACCP plan. This plan, I believe, is in your notebook under tab E, under sub-tab (c). And among the features there, it indicates that this plan does not apply to gift fruit shippers, retail processors, and roadside stand operators engaged in the production of fresh squeezed unpasteurized juice and who squeeze less than 30,000 boxes annually.

On the next page, you will see that as far as the wash area there are items like acid wash and so on, 200 parts per million, hypochlorite, brush rollers and so on. And there is further quality control checks indicated in the plan under item D indicating that there is micro-monitoring required using a standard plate count, coliforms and E. coli as indicators of the process, and I don't believe we heard any data on generic E. coli testing yesterday.

Martha indicated that the oversight is divided between USDA and the Florida Department of Ag. USDA has oversight over the large producers. She had indicated over 40,000 boxes squeezed a year, maybe it's 30,000, but, anyway, in that ballpark. And Florida Department of Ag has oversight over the smaller juicers.

They have been monitoring the smaller producers for E. coli and coliforms and have found no generic E. coli and only a few coliforms early in the--positives early in the program.

The other thing she pointed out is that while the micro quality of juice squeezed on site under this program was good in her view, this program, this code does not preclude transporting juice in from outside the state where the production is out of the control of the producer. And I believe that's it.

Thank you.

MS. OLIVER: Okay. I would ask Dr. Parish or Dr. Ismail if you had anything to add to that briefly that you felt should be clarified.

DR. ISMAIL: I think there are several--

MS. OLIVER: Can you please identify yourself and go to a microphone just so everybody can hear you? Thank you.

DR. ISMAIL Mohamed Ismail, Florida Department of Citrus. There are several plans that have been mentioned yesterday as the Florida HACCP plan, and they are adopted by well-established companies, and they are very well

researched. A great deal of expenditure of funds have been spent on developing these plans, and they are definitely much stronger than what the regulation in our books mandates.

There are some discussions as far as bringing in tanker juice into the State of Florida and the desire to regulate in some fashion the quality of these arrivals. But the HACCP plan is indicated in the regulation. You might see it mentioned as verification through a GMP or HACCP or quality control measure. I believe--I don't have it with me right now, but it is indicated as "or a HACCP plan or quality control or GMP." So HACCP is one of the options that could be adopted by a juice manufacturer.

MS. OLIVER: Okay. Thank you.

Dr. Parish, did you have anything to add?

DR. PARISH: No.

MS. OLIVER: Okay, fine. Thank you.

With that behind us, then what I'd like to do is remind all the Committee members that we presented you with a list of questions yesterday, and the questions are basically reflective and basically what was in our request for comments and in our Federal Register notice.

I'm going to read the questions that are presented for the record, once again, so it is the record--Alison?

DR. O'BRIEN: May I just clarify?

MS. OLIVER: Sure.

DR. O'BRIEN: You said today we will focus on fresh squeezed juice. You still mean citrus juice?

MS. OLIVER: Citrus.

DR. O'BRIEN: Thank you.

MS. OLIVER: Yes. I want to say a couple of things. You know, obviously in asking these questions, FDA's focus is safety and public health, and I want to put that in the background. And these are the questions that we're asking the Committee, and there are two groups of questions: one dealing with internalization and survival of pathogens, one dealing with application and measurement of the 5-log reduction standard. I'll go through and read these questions for the record.

For the internalization and survival of pathogens, we had four questions:

Is it valid to assume that there is no internalization of pathogens in citrus fruit?

Is internalization of pathogens into citrus fruit theoretically possible?

If internalization of pathogens into citrus fruit is theoretically possible, is such internalization likely to result in a public health risk?

If internalization does occur and it results in a public health risk, are there techniques to assure that internalization of pathogens does not occur? If so, what are they?

Regarding the application and measurement of the 5-log reduction standard:

At what point in the production process should a processor begin to measure attainment of the 5-log pathogen reduction? For example, should fruit be cleaned and culled before measurement of the 5-log reduction has begun?

Are there limits within which the 5-log reduction must be accomplished?

Would using cumulative steps that are separated in

time and location impact a processor's ability to achieve and deliver a 5-log reduction?

Can the safety achieved by the 5-log reduction be maintained consistently if a processor does not package product immediately after attaining the 5-log reduction?

They are the questions that we're looking at, and the two areas, once again, internalization of the pathogens and application and measurement of the 5-log reduction, and they're the areas that FDA would like the advice of this Committee on.

What I'd like to do now is ask the Committee--I know there were a number of people who did not get a chance to ask questions of individuals yesterday. The individuals who were presenters are still here today, and I wanted to give you that opportunity to ask questions of clarification.

Once again, this is time for the members to ask any additional questions that they have for those who made presentations yesterday. It's not for discussion or debate, but to help clarify what you heard or read, and the questions are for the Committee to ask. Then there will be opportunity for the Committee to enter into further discussions after that.

The other thing is there may be one or two people, because some individuals felt that they might not have been able to answer some of your questions yesterday, that might be here to supplement and better answer some of those questions. So, with that, I'd like to go and open it for questions of clarification.

Okay, Bill?

DR. SPERBER: Thank you. I'm Bill Sperber from Cargill. I have a question for Dr. Strobos. I believe I saw him this morning.

It seems that many of the juice processors, in attempting to comply with the 5-log reduction, are putting heavy emphasis on fruit selection and fruit washing. However, in your presentation, you made reference to a reduction in extraction, which was kind of new for me. I hadn't heard of that previously.

You described an experiment in which fruits were somehow dipped or treated with a suspension of 106 organisms per ml, and then I don't know how the fruit was handled after that. And then when you extracted the juice, you reported 103 organisms in the juice, and you claim that as a 3-log reduction.

I was wondering if you could perhaps describe that experiment in more detail so we could understand that.

DR. STROBOS: In part, that's described in some of the earlier materials as well as it's also--just for your reference, it's also described in the Florida symposium for which you have the transcript.

The concept is really how do you--assuming that there may be some residual small contamination of the surface, how do you avoid contaminating the juice as you extract it? Because as I'm sure most of you who have done hand extraction know, you get juice on your hands and also on the peel when you use some sort of cone compression device.

There is a specific extractor, largely put on the market by FMC, which basically stabilizes the orange, a cold orange. It stabilizes the orange and then induces a puncture in the bottom and then sucks the juice out.

The experiment that we did to evaluate the effect of that reduction method was by, you know, inoculating the surface of the orange with microbial contaminant, and then without sanitizing the orange and measuring the levels of residual organism on the surface of that orange, you know, calculating basically the--or measuring the amount of residual organism in the juice itself, you know, using a contaminated orange. So, in other words, when you have the orange completely contaminated, so covered with organisms at a level of about 106, 107 measured, you know, what kind of residual levels do you get in the juice from that orange?

Does that explain--there's more detail provided in two sets of documents. One is at tab 3 where there's a discussion of the experimental protocol, and the other is at--I think it's--actually, I think that's tab 2, and then there's tab 3 where the data from that experiment are actually presented.

DR. SPERBER: Two things. I'm thinking that it's difficult to extrapolate from surface count per square centimeter, say, to a volumetric count of extracted juice. So it might not be accurate to say that you had a 3-log reduction. Perhaps it is, but there's a difficulty there in counting.

DR. STROBOS: Well, the way that was done was by taking a template, swabbing the--a measured template. We know the surface area of an orange, and we took, you know, a specific surface area, a known surface area of the orange, swabbed that, did counts on that, and extrapolated that to the entire surface of the orange, and then assumed that that amount of organism had gotten into the juice and used that as the reduction.

We've also done, you know, sort of start-to-finish measurements subsequent to that which have verified that, and then to a certain extent, you know, the data we presented yesterday also show very similar results.

DR. SPERBER: Thank you.

A further complication of this type of experimentation might come up more during the discussion today, and that is, when we're trying to validate a process, it's hard to do it under artificial laboratory circumstances where the organisms might not be attached to the fruit the same as if they had occurred naturally and lived in the grove on the fruit for weeks or whatever. So it's something to keep in mind.

Thank you.

MS. OLIVER: Fine. Thank you.

Bob?

DR. BUCHANAN: Thank you, Janice. I also have a question for Dr. Strobos.

MS. OLIVER: Can you please identify yourself?

DR. BUCHANAN: Bob Buchanan, Food and Drug Administration. I also have a question for Dr. Strobos.

I was wondering, Janice, if it--since--instead of making Jur jump up and down and some of the other speakers, would it be appropriate to find them some seats at some place close to the microphone.

MS. OLIVER: Well, there's a seat next to me, and there are some chairs that can be brought up near the microphone up there for people.

DR. BUCHANAN: Dr. Strobos, you indicated yesterday that the consortium of four companies that you

represent have all voluntarily--whether they're in Florida or not--agreed to follow the Florida program. As part of that Florida program, there is a requirement for testing for E. coli, generic E. coli, as indicators of process control. However, you didn't share that data with us yesterday.

Do you have that data available? And could you share it with us?

DR. STROBOS: Yes, I--as you may be aware, having reviewed the Florida program, there's a requirement--and I'm not a microbiologist, so you may have to help me with this. But there's a requirement for testing what I believe are referred to as generic coliforms. There's a requirement for looking at fecal coliforms, and I believe there's a specific requirement for looking for generic E. coli, as well as a requirement for looking at pathogenic E. coli.

DR. BUCHANAN: Just so we all know what phrase I'm talking about, this is in the program, and it says, "The program must include a microbiological monitoring component using standard plate count coliform and E. coli as indicators of process control."

DR. STROBOS: Right. My understanding is that at this point the two--remember, in the consortium there are four companies, and as was apparent, I think, from yesterday's data, the two companies in California have been gradually coming on line with this sort of complete testing over the last few years.

My understanding in the California companies is that they have been doing--and, again, I'm not an aficionado on the testing, and I could certainly bring someone up from one of the companies to discuss it in more detail. But my understanding is that they are doing a generic coliform test and then there is a way to evaluate fecal coliforms in that test. But the two California companies at this point are not specifically testing for generic E. coli.

With regard to the Florida companies, since they're under the mandatory HACCP, they are, in fact, testing for generic E. coli. One company informed me that they had had no positive results. Another company informed me that they have had, over the entire 7,000 tests they've performed, about 20 positive results, and none in the last year. All of those have occasioned some sort of a failure investigation.

DR. BUCHANAN: And for the California plants, do you have the fecal coliform data?

DR. STROBOS: No, I don't have that, but I could probably put that together. I think at this point the companies don't particularly want to identify themselves, so I would be a little loath to bring up a particular company and address that question, but I could certainly respond to that in terms of the fecal coliform, if you can give me a few minutes to track that down.

DR. BUCHANAN: Sure.

DR. PARISH: Jan, may I respond to that?

MS. OLIVER: Sure.

DR. PARISH: Mickey Parish, University of Florida.

Bob, as I understand the regulation--and I'm not a regulator, which is one of the reasons I didn't respond to your question earlier on regulations. The regulation requires, as I recall, total counts, yeast and molds, generic coliforms, and E. coli. There is no requirement, to my knowledge, for fecal coliform specifically, which, to me

has always been a weakness with that particular regulation.

The--well, that's all I wanted to say.

MS. OLIVER: Okay. I was just handed the Department of Citrus chapter on the quality control, and it says, "The program must include a microbiological monitoring component using standard plate count coliforms and E. coli as indicators."

Okay. Bala?

DR. SWAMINATHAN: Thank you, Madam Chair. Bala Swaminathan, CDC. I have two questions, one for Dr. Miller and one for Dr. Parish and any of the experts on processing. I will ask my question first to Dr. Miller.

In your manuscript, you indicate that the mean pH of the orange juice used in the experiments was 3.65. But I did not see any information on the pH of the oranges themselves. and also in the manuscript, you indicate that California Valencia oranges were used exclusively in your investigation, but I think in your presentation you mentioned that oranges from Florida and California were used.

My questions are: Were any pH determinations made? Of the seven out of 178 that yielded pathogens after the internalization experiment, were they all predominantly from one state or the other? And were the ph's measured in those oranges?

DR. MILLER: This is Art Miller. I may need some clarification. I've been scribbling these down.

You asked about pH in the juice, which I agree, that was 3.65. We didn't measure the pH in the orange, and I would emphasize the fact because of the compart--the way that you take pH of most products is to make a homogenate, so in this instance, with this commodity, you take the commodity and turn it into juice. So we measured the pH of the juice, not the orange. But I would expect to have compartmentalization. If you can insert a probe into the different areas, you'd probably have different pH's.

I'm getting a little bit fuzzy on your questions--you asked about Valencias. For the first set of studies--let me just make sure I'm--

DR. SWAMINATHAN: Do you want to repeat the question?

DR. MILLER: Yes, but I want to make sure that I have my breakdown properly.

All right. For the dye uptake studies, we used both California and Florida fruit. For the pathogen uptake studies, we used California Valencias.

DR. SWAMINATHAN: Okay.

DR. MILLER: I think that was your question.

Then there was another question about pH.

DR. SWAMINATHAN: No. You've answered my question because my question for the internalization of pathogen was if you used oranges from California and Florida, of those seven oranges that were found positive, did they call come from one place or the other? But since you used California oranges exclusively, we don't need an answer for that. Thank you.

DR. MILLER: All right.

DR. SWAMINATHAN: The next question is for Dr. Parish, and in order to answer the first two questions, we need to know whether it is possible under any circumstances to have a 17 degree Celsius difference between the fruit and

the water or the solution in which it's immersed during any stage of processing, either in Florida or in California. If you don't anticipate--the second part of that question is: What is the maximum likely difference in temperature between the fruit and any water or solution used for immersion that's likely to be encountered in processing?

DR. PARISH: My name is Mickey Parish. Those are very good questions. I cannot speak to California specifically.

In Florida, I would not expect--are you referring to on-tree in the grove situations?

DR. SWAMINATHAN: Anywhere.

DR. PARISH: Okay. In a grove situation, I would not expect a 17C differential in temperature due to passing thunderstorms or rainstorms, something of that nature. I would not expect that.

In a plant situation with fruit arriving from a grove that has been picked and then put onto conveyor belts to undergo washing, the differential there would be whatever the ambient temperature of the fruit is versus the temperature of the water.

We could expect fruit to probably come in at ambient anywhere--let's say an extreme case might be harvesting in the late part of the season in June where the ambient temperature may be 33 or 34 C and the--I'm going to guess--the municipal water temperature in Florida, believe me, is not nearly as cold as it is around here. It's sometimes not nearly cold enough. I'm going to make a stab at that at probably around 80 Fahrenheit, 75 to 80 Fahrenheit, and if you'll do a conversion for me, I would appreciate it.

DR. SWAMINATHAN: And the temperature of the fruit was between 33--

DR. PARISH: Let's say the temperature of the fruit was probably about 95 Fahrenheit.

DR. SWAMINATHAN: So it is possible to have a 20-degree difference, as much as a 20--

DR. PARISH: Fahrenheit.

DR. SWAMINATHAN: Fahrenheit.

DR. PARISH: Yes.

DR. SWAMINATHAN: Thank you.

MS. OLIVER: Bala, did you have any other questions?

DR. SWAMINATHAN: No. Thank you.

MS. OLIVER: Okay. Dr. Strobos has some clarification in answer to Dr. Buchanan's question from before.

DR. STROBOS: In terms of the fecal coliform testing being done in California, one California company hasn't identified any positives. Another California company had two last year, but has had no positives this year. Last year's batches that had positive coliforms were destroyed.

MS. OLIVER: Jim Anders?

DR. ANDERS: Yes, I really have two questions. Part of it was just answered by Swami, so--

MS. OLIVER: Can you identify yourself, please, for the record?

DR. ANDERS: Oh. Jim Anders, North Dakota Health Department.

Yes, I have two questions, one for Dr. Miller. I was also concerned about the temperature that the FDA

studies were done at. Twenty-one degrees Centigrade is approximately 69 degrees Fahrenheit, I believe, and 4 degrees, of course, is much colder than that.

First of all, I understand why that study was done because of the differential to see what would happen with the dye uptake. But from what we're hearing, none of the temperatures in the processing of these plants are at those temperatures. So I have a big question about that.

DR. MILLER: Let me mention one point that I think is important to bring out. In the pathogen uptake study, we took the oranges and moved them from room temperature to a 4-degree incubator and held them for three hours. So at no point did they equilibrate at 4 degrees. In fact, when we measured the internal temperature, it was 11 degrees, so that differential is not quite as high as just subtracting the difference between the two extremes, 21 to 4.

I think your question asked what was our rationale, and simply stated, it was laboratory convenience.

DR. ANDERS: Well, yes, and my point is that none of those temperatures--either one of those temperatures, actually--is used within the industry, or at least that's what we're hearing. I really don't understand why it was set up with those temperatures.

DR. MILLER: The question really was that we were trying to address is: Can it happen? And, once again, I would emphasize the fact that it really wasn't a 4-degree orange; it was closer to an 11-degree orange.

DR. ANDERS: Okay. Thank you.

My second question is--and I really didn't get--I did ask Dr. Ismail yesterday, and he said he didn't have the answer to it. But it seems to me that this is really an important issue.

In the process of oranges going through--coming into these plants, the way I understand it is that, by sight, the worst-looking oranges are immediately sent someplace else. They're not going through the processes.

So then my question is: Where are the studies to tell us how many actual pathogenic E. coli or Salmonella organisms are left on any of the oranges that are left that are going through the process? Are there any studies? Is there any information on that that might tell--

DR. ISMAIL: Not that I am aware of. I don't think anybody has taken the time to do a systematic evaluation of what is really left on culled fruit, eliminated fruit. So there is a gap in our knowledge.

DR. ANDERS: Well, it's a tremendous gap because we're talking about what we need to do here, and we don't even know if there are any organisms left or what numbers of organisms are left on the oranges.

DR. ISMAIL: Most likely the predominant organisms that you would find on eliminated fruit are decay, pathogenic organisms, plant pathogens, like diploidia, penicillium, and perhaps yeast and different molds.

DR. ANDERS: And as we discussed yesterday, most of those are not really pathogenic to human beings--

DR. ISMAIL: No, they are not.

DR. ANDERS: --that are non-immune or don't have immune problems.

DR. ISMAIL: Correct. In reference to what Dr. Miller has mentioned, I believe the study by the Food and Drug Administration raised the temperature. The fruit was

incubated at 37 Celsius, then placed a 4 degrees Celsius for three hours. The core temperature of the fruit went down to 11; however, the surface temperature of the fruit must have been much higher. There is a gradient in temperature decline, and you would find that to be true in any study where temperature reduction is involved. So the surface of the fruit definitely, I can say, should have been much lower.

DR. ANDERS: One additional question, and maybe you won't know this. So we went through the basic throwing away of the bad fruit. We got those out of the way, and assuming that the fresh juice industry now is going to take the best fruit or some of the very best fruit, there are no studies then for the oranges that they're starting out with, there are no studies to show what kind of contamination--and I'm talking about now pathogenic contamination, E. coli and Salmonella, on the fruit that they are actually starting in this process.

DR. ISMAIL: On the fruit that is--

DR. ANDERS: Going into the fresh fruit now. We're really talking about two things. One was in the basic process of oranges they are culled and the best fruits are taken out, and then the way I understand it is that the fresh juice industry then takes the best fruit and then goes through the fresh juice process.

Are there studies to show what kind of pathogens are present--prevalent on oranges as they start that process?

DR. ISMAIL: I believe there are some studies that show that there are different mold, bacteria, yeast. Have they been characterized? I'm sure there has been some characterization. But there has been no Salmonella or E. coli 0157 detected on any fruit that is going into either fresh fruit or juice.

DR. ANDERS: I'm sorry. I keep--it's an important issue here. Therefore, if there were contamination at the end of the juice, is that to be inferred, then, that since there isn't any to start with, you can't come up with something that--I mean, you can't come out with something if it wasn't there at the beginning.

DR. ISMAIL: I think this is a fair conclusion.

DR. ANDERS: So it was contaminated in the process, from an outside source, then, not from the oranges themselves.

DR. ISMAIL: We believe that most of the problems associated with the juice contamination in general, whether it is fresh or not fresh or pasteurized, has been introduced at some point perhaps during the extraction process, due to breakdown of good manufacturing practices, or sanitation was lacking.

DR. ANDERS: Thank you.

MS. OLIVER: Dr. Parish had something he wanted to add to your question. And if you could identify yourself fully for the record? If I could remind everybody once again, when the speakers come up to answer the questions and the Committee members, to once again just identify yourself just for facilitating the transcript. Thank you.

DR. PARISH: Mickey Parish, University of Florida.

In answer to your question a little more, at least in the studies that we did on the plant that was involved in the salmonellosis outbreak in '95, we did look at surface

microflora before extraction, looking specifically for Salmonella, and we found none.

In looking at the literature in the past and trying to find examples of where people have looked for human pathogens on the surfaces, I found very little information. There simply is not much information on what types of organisms can be found on the fruit surfaces. And as an aside, I applied to USDA NRI last year to do that very thing and was told that the research was not relevant to food safety.

MS. OLIVER: John?

DR. KVENBERG: Thank you. John Kvenberg, Food and Drug Administration.

My question of clarification goes to Dr. Arpaia or others who spoke yesterday that might be able to help the clarification, and that is, in a description outside of the State of Florida, specifically in your presentation on California, it was described, a situation where the packinghouse operations and how oranges were treated, are oranges specifically in California, to the knowledge of those who spoke yesterday, similarly treated? And is the same oversight there where--or are there direct contract oranges that are going to juicing that do not go through a packinghouse operation?

DR. ARPAIA: Mary Lu Arpaia. If I understand your question correctly--just let me restate it--you're asking whether it would be possible for a grower to sell his fruit to a juice contractor directly. To my knowledge, that does not occur in California. All the fruit that would be going to fresh juices would be predom--almost exclusively, as far as I can tell, would be going directly through a

packinghouse operation in California.

As I indicated, Sunkist packs about 55 percent of all the oranges, and Mr. Orman told me yesterday that all Sunkist growers then would send 100 percent of the fruit exclusively through a Sunkist packinghouse. The other major houses also would be--are mainly growing their own fruit and do some contract packing. And, again, usually those contracts are set up so that you pack--you send 100 percent of your fruit through the packinghouse.

I'd just like to clarify the question about temperature differentials. Our navel oranges are harvested from approximately October through May. Most of the navel oranges come from the San Joaquin Valley. During the time of harvesting, the ambient temperatures can be anywhere--they normally pick them in the middle of the day, and the ambient temperatures during the winter months can range from about a low of about 45 to about 65 or 70 degrees Fahrenheit. We don't pick the fruit when the conditions are damp or moist, when it's foggy, because when the fruit are wet, they're very turgid and they're very susceptible to mechanical damage, and then you can have a lot of losses on arrival due to rind blemishes. So the practice is not to pick the fruit unless the fruit is dry on the trees.

We don't like to run the fruit when the pulp temperature is below 50 degrees Fahrenheit because it's very difficult to apply a good wax application. Typically they like to have the fruit warmer, around 68 to 70 degrees, before they apply the wax. The water temperature, again, is--the ambient is usually above 60 degrees in California.

During the summer months, when we harvest Valencia oranges, again, most of the Valencia oranges now are coming from the San Joaquin Valley, although we have Valencia oranges coming from Ventura County and in the Coachella Valley. The Coachella Valley harvest season is from about the months of February through May. They have much higher ambient temperatures during that period of time, anywhere from about 70 degrees Fahrenheit to 100 degrees Fahrenheit.

They have thermal source waters in the Coachella Valley, so the water actually is usually quite warm. A minimum temperature of about 70 degrees would be the water temperature in the Coachella Valley.

In Ventura, they harvest the fruits in the late summer months because most of that fruit goes to export, and, again, the ambient temperatures there would be 70 to 85 degrees, approximately, during the day, and the water temperature, again, is quite warm. They need the water to be fairly warm, again, for all the solutions that they use, especially the wax solution.

Then addressing the Valencia oranges in the San Joaquin Valley, they're picked from about May through August. Temperatures can range from about a minimum of about 75 degrees during the day to in excess of 100 degrees. We don't like to pick the fruit when it's very hot, but typically the fruit will be brought in and held overnight so that they can have some cooling. Some houses have cooling facilities, and, again, the fruit are run--they like to run the fruit when the pulp temperature is about 68, 70 degrees Fahrenheit. But we never run cold fruit in warm water, and we don't run warm fruit in cold water.

MS. OLIVER: Okay. I just want to--this is another logistics question. I just need to tell everybody that all the microphones are on so that when we have discussions at the table, it sometimes is going and it makes it more difficult for the record, we were told. Also, if individuals would bring your microphones forward since they are all on, the volume is not that high, so when you speak, we need to just assist the recording a little bit.

Okay. Dr. Beuchat?

DR. BEUCHAT: Yes. I have a question for Dr. Strobos I'm trying to understand the procedure in more detail that was used for your study with the dye and the Salmonella. Correct me if I'm interpreting this incorrectly.

You dipped the oranges in a suspension of cells, and that suspension contained approximately 106 per ml. Is that correct?

DR. STROBOS: Yes, with the--we're talking about the most recent experiments that we did just last October. Yes, that would be the case.

DR. BEUCHAT: And the baseline against which you then made calculations in terms of reduction in numbers or differences in numbers in the juice versus that population, was that the difference--I mean, did you--I heard you tell us that you used a swab technique to determine populations per--was it orange or square centimeter?

DR. STROBOS: Yes, per square centimeter of the orange surface, but that was done in the earlier studies.

DR. BEUCHAT: Okay. I guess I'm--it's difficult to--I don't know how many milliliters of juice was extracted from each orange, so it's difficult to compare surface

versus volume in these studies.

DR. STROBOS: Yes. I mean, that is one of the experimental--what I think of as the laboratory problems with these studies, and that is that we're trying to go from a surface area contaminant to, you know, what the contaminant is in the volume of the juice.

Now, we do know, you know, on average--we're doing, you know, relatively large numbers and then juicing ten oranges at a time, and we do know what the average volume of the--you know, how much juice you get out of each orange, which is a fairly, you know, narrow range. And we do know what the surface area of the oranges is on an average basis as well.

DR. BEUCHAT: Was there a study done along the way to confirm, to validate that all of the cells that had attached to or adhered to the surface of the orange were indeed extracted using the swab technique?

DR. STROBOS: You mean some sort of a microscopic examination of the--

DR. BEUCHAT: Well, yes, some microscopic or mass balance through culling forming units that you could have extracted using that technique.

DR. STROBOS: Not specifically, although when we were doing the swabbing technique, the concentrations of organisms that we were getting--and this, again, I would have to--I would probably have to refer to the data. But my recollection is that there was a drop between the concentration in the contaminating--or the inoculating fluid and the amount that was recovered through the--you know, the swab technique. Our assumption was that that was due not--you know, just to the sticking issue. We did not--other than that, which is not a mass balance analysis.

DR. BEUCHAT: Another question. You may be able to answer this, or someone else. The specialized mechanical device that FMC has on the market and has used, how many--or what percentage of the fresh citrus juice processors actually use this particular machine, equipment?

DR. STROBOS: Of the four companies that have been part of this consortium, all of them use it, and use it exclusively. My understanding is when you go out into the rest of the fresh juice industry in Florida that it is the predominant machine used, but I believe there may be some residual companies that are using different extractors. I'm not 100 percent sure on that. I think at this point everybody has switched. Outside of Florida, I wouldn't know the answer to that.

DR. BEUCHAT: One last--

DR. STROBOS: Now, I--yes, go ahead.

DR. BEUCHAT: Excuse me.

DR. STROBOS: I had just--there was a clarification with regard to the question on whether packing in California that I--let me let you continue your question because I just wanted to make sure--

DR. BEUCHAT: Either in California or Florida, over a period of a year or several years, are there citrus fruit transported by land from east to west or west to east that are subsequently used in fresh citrus juice production? And, also, I would extend that further. Are there any imported citrus fruits that are used in the U.S. for the fresh citrus juice market?

DR. STROBOS: It would be speculative for me to

answer that, but I can certainly find that out in the next few minutes and respond to that question.

DR. BEUCHAT: My question is not so much in terms of perhaps different microflora that may be on these fruits but, rather, fluctuations in temperature and pressure that they would be subjected to during this transport, even by land, across the U.S.

Thank you.

DR. STROBOS: Okay. I can--just in clarification, I just wanted to be clear that I think we're all aware of the fact that California does not have the same set of rules governing fresh juice operations and that it's, you know, the position of the people I represent that we want to have that system as a national system.

With regard to the two companies in California, they buy their fruit directly from the growers. They do not buy them from packinghouses. There are some fruit that does come from packinghouses, especially, my understanding was, last year, when there was some frost issues in terms of the temperature. Both of the companies, however, do, you know, complete processing from the arrival of the oranges basically in terms of, you know, grading, washing, sanitization, which is why we could say that none of the fruit used in the fresh juice operations in these two companies were immersed.

DR. STROBOS: Mike Doyle?

DR. DOYLE: This is Mike Doyle, University of Georgia. My questions also are for you, Dr. Strobos, so don't go too far.

I'd like to follow up on E. coli questions. As I understand it, in Florida, the Florida model requires that you do E. coli testing. Is that correct?

DR. STROBOS: That's my understanding, yes.

DR. DOYLE: Now, if you do E. coli testing, do you hold the fresh juice until the testing results are in?

DR. STROBOS: My understanding is that as part of the regulations that is not required.

DR. DOYLE: So if you come up with a positive for E. coli, what's the next step?

DR. STROBOS: Well, again, the question becomes what the companies are doing in terms of what the regulations require. My understanding is that the way in which the fruit is distributed, the companies, in fact, have control over--remember, it has a 17-day shelf life by regulation. However, the companies have control over the juice for a period of time after it's been juiced, and many of the company--first of all, we haven't had, you know, positive E. coli results recently.

In the circumstances in which positive E. coli results have been obtained, my understanding is that the juice has been able to be recalled before distribution to consumers in those specific settings.

DR. DOYLE: So then if there is a positive E. coli, the juice would not be sold. It would not be made available to the public.

DR. STROBOS: You know, we're certainly attempting here to be responsive to the concerns of the community as well as the concerns of this Committee with regard to ensuring the safety of juice. You know, there's a difference between what the current regulations in California are and the current regulations in Florida and

national regulations. And we're certainly looking for recommendations from the Committee on the best ways to do these things.

When it comes to the issue of release of product relating to microbial testing and the timing of that, my understanding is that the companies that were involved here have generally been able to not distribute product that has had positive E. coli, generic E. coli testing. They have been able to do that, but I do not believe as originally designed--and perhaps Dr. Ismail may want to comment on that as well, but as originally designed, the concept of the E. coli testing was as part of, you know, a GMP or a HACCP-type program, so that the concept was that you would evaluate the results in light of what your processing was and attempt to do failure investigations when those events occurred. And it was not designed to be sort of as a release testing format, and that it was the concept, I guess--if I understand, you know, HACCP, it is that you have a series of controls, not just one control, and that the goal is, therefore, to use these microbial testings as one in a long series of controls but not as the sole control with regard to the processing of the juice.

DR. DOYLE: Would you consider the presence of generic E. coli to be an indicator of potential pathogens being present?

DR. STROBOS: I think that the presence of generic E. coli probably indicates a problem with the manufacturing of--you know, and requires some sort of an investigation.

Again, I'm not a microbiologist, but my understanding is that some E. coli are not pathogenic, and, therefore--and you can probably answer this question better than I can. But my understanding is that the mere presence of E. coli doesn't mean that it's a public health issue. It does seem to me to indicate that because of the origin of E. Coli there is a problem that needs to be investigated and identified.

DR. DOYLE: That's all I have. Thank you.

MS. OLIVER: Peggy?

DR. NEILL: Peggy Neill. I'm struggling with something, and I think I'm probably not alone, and it has to do with this issue about testing and the results.

It has been a time-honored scientific tradition to fully describe sampling plans, conditions under which samples are held prior to testing, the testing methodology, and in particular, its lower limit of detection, sometimes called sensitivity. I think in the best interests of the Committee it would be extremely helpful for us to be able to assign credibility to the results that have been mentioned repeatedly by several groups about the testing that has already been done over the last couple of years, both in Florida and in California. And to that end I would appreciate it if those details could be cogently summarized for the Committee.

I think this is probably best directed to Jur Strobos, but if John Martinelli or Dr. Ismail or Dr. Parish, if someone has those level of details, they would be, I think, fairly helpful for us to be able to look at this issue

MS. OLIVER: Let me ask a question. Do any of you have that level of detail that you can respond to now? Do you need to go off or at break time for a few minutes and

respond back after that? Which would be the best way?

DR. STROBOS: You know, again, not being a microbiologist, I certainly understand your concerns, and my understanding is that the test--you know, the test methodologies that have been used to evaluate the various different tests that Florida has required are standardized, and many of them, in fact, when FDA was involved with the Orchid Island plant, were, in fact, proposed or recommended by FDA.

Not being a microbiologist, I don't know the significance of the description or the level of detail that you would require, so I think it would be better for me to try to develop a more formal response that you would be able to understand and evaluate in a cogent manner.

MS. OLIVER: Dr. Ismail?

DR. ISMAIL: Yes, I left my notes here. I'm glad I came back.

All our scientists--and I'm speaking of the Department of Citrus, and I think I can speak on behalf of Dr. Mickey Parish--direct their work to be published in refereed journals, and we have a very thorough process by which our manuscripts are reviewed internally at the Citrus Research and Education Center, University of Florida at Lake Alfred, and that process is very exhaustive. That's before even the paper leaves the premises to be sent to the journal. And the details of the methodology, the experimental conditions, where the fruit were obtained, how it was held prior to extraction and so on, are always recorded and detailed.

You have been provided several manuscripts that have already been published by Dr. Steven Pao, and the latest work has been hurried. However, it was exhaustive. He has worked many times 14, 15 hours a day, weekends, repeated some of the experiments that you have seen results of and been extremely cautious, extremely conservative in putting his results. And he definitely would be more than happy to provide details on how the fruit was handled throughout the steps until the final results were obtained.

MS. OLIVER: Okay. I talked to Dr. Strobos for a minute, and he indicated that if he had a few minutes after break that if they got together, they would be able to respond better. So we'll probably break around 9:45, and then after that, we'll get that response. I think it would be better if they, you know, could discuss and come back with that.

Dr. Parish, do you have a response for that now?

DR. PARISH: Just very briefly. The test methods, as I understand it, vary from plant to plant to a certain extent. I do know that at least--and with Orchid Island's permission, referring to what they do, that the test methods they are using are bam methods. They do sent the test samples out. The degree of sensitivity, at least for--well, it's hard to say what the degree of sensitivity is at this point.

I would point out that with respect to the requirement in the Florida regulation for total coliforms--and this is something that I had a disagreement with when this regulation was being brought up. Total coliforms are really of little use in citrus simply because there are so many non-fecal coliforms that do exist naturally that could potentially get into juice, and I just wanted to point that

out.

MS. OLIVER: Okay. And we'll have a further response after break.

Peggy, did you have anything else?

DR. NEILL: No.

MS. OLIVER: Okay. Bob?

DR. BUCHANAN: Thank you. I have--

MS. OLIVER: Please identify yourself.

DR. BUCHANAN: Bob Buchanan, Food and Drug Administration. You'll train me eventually.

I have two questions, and I think they both will include Dr. Arpaia and Dr. Parish. One was a further clarification on the temperature differentials that were discussed. I'd like to know what is the temperature of the cold rooms that you use in your facilities. Two, what is the temperature of the oranges before they enter those cold rooms?

If I can get that from the California and Florida perspective, then I have another question for both of you, also.

DR. ARPAIA: The temperature of the cold rooms are generally set at 5 degrees Celsius. The fruit--most of the rooms do not have any forced-air cooling facilities or room cooling, so the fruit will enter the room from the packing line. They may be on the floor for a while. The packinghouses are normally run at ambient temperature. So--

DR. BUCHANAN: So we're talking about a 75-degree Fahrenheit to 5-degree Fahrenheit differential?

DR. ARPAIA: Going into the cold room?

DR. BUCHANAN: Mm-hmm.

DR. ARPAIA: The packinghouses, like the one that I was in on Wednesday that I took the photographs that I showed you yesterday, there was very little temperature differential between the outside temperature and the temperature of the packinghouse. But it was a warm day, so it was about 65 degrees outside, and the fruit goes into the cold room, and the cold room is at 5 degrees Celsius or 41 degrees Fahrenheit.

So the fruit is going in--the fruit does warm up when it goes over the line, so it would be reasonable to assume that the fruit would be at approximately the temperature that the packing--that the main portion of the packinghouse is at. But that will vary for the time of year because they will run coolers in the packinghouse during the summer, and they will run heaters in the packinghouse during the winter when it's very cold.

DR. BUCHANAN: On average, you're talking about somewhere about--

DR. ARPAIA: Ambient.

DR. BUCHANAN: --70-degree Fahrenheit differential?

DR. ARPAIA: Well, 70 degrees going into--70 degrees--

DR. BUCHANAN: Oh, no, I'm sorry. Yes, I--

DR. ARPAIA: Yes, 70 degrees Fahrenheit--

DR. BUCHANAN: About a 20--

DR. ARPAIA: --in the packinghouse facility and the fruit are generally put at about 41 degrees Fahrenheit. The fruit does not normally stay in that cold room for very long. It's loaded on the--they try to get the fruit out of the holding room. It's basically only holding rooms. It's

not cold storage rooms like you would think for apples. So the fruit goes into it, typically the fruit will only be in that holding room anywhere from less than 24 hours through two or three days.

DR. BUCHANAN: But we're talking about somewhere--I'm trying not to mix and match my degrees Celsius and degrees Fahrenheit, but somewhere between a 15- and 20-degree Celsius differential between ambient temperature in the packinghouse and in the cold room.

DR. ARPAIA: In the cold room, yes.

DR. BUCHANAN: Okay.

Dr. Parish, are the cold rooms within Florida held at about the same temperature?

DR. PARISH: Yes, the cold rooms are held at roughly 5C.

DR. BUCHANAN: And the ambient temperature of a packinghouse in Florida?

DR. PARISH: I can't answer packinghouse specifically because I don't work with packinghouses. But in processing plants, it would be roughly ambient temperature, that's correct.

DR. BUCHANAN: And that would be--in Florida, what would be the average ambient temperature?

DR. PARISH: During harvesting season, which runs typically from about November through May, perhaps October through June, we're talking a large fluctuation ambient temperature, anywhere from--well, perhaps as low as 60 degrees Fahrenheit to as high as 90.

DR. BUCHANAN: Okay. So, again, you're talking--

DR. PARISH: That's outside temperature. Inside, probably more in the range of 75, 80 degrees. I think it would be very similar to California.

DR. BUCHANAN: So potential temperature differential between the cold room and the ambient temperature would be in the range of anywhere from 10 to 25 degrees Celsius?

DR. PARISH: Anywhere from--yeah, I would say it's very comparable to the California situation.

Let me point out that I know of probably two of the larger processors that do run fruit through a packing line so that it is waxed and is then put into cold storage for extraction at a later date. The majority certainly of the small people do not do that because they don't have that sort of facilities, holding facilities. The mom-and-pops, the roadside stands, would not be able to do that. But a couple of the larger facilities, to my knowledge, do store fruit under cold storage. When the fruit is brought out at that point, Bob, at a later point for extraction, it is re-washed, re-graded, even though it's already been through a packing line, it's put through the whole line again just to make sure that they do take out any fruit that may have softened or may have some bacterial rots or something.

DR. BUCHANAN: Now, the second part of my question is an abrupt shift, but it was a question I had yesterday and didn't have an opportunity to ask.

It was mentioned that the culls go to animal feed, and I know from visiting Florida and California that you have a very substantial beef industry in both locations, animal production. Is there any restriction on the adjacent location of animal-rearing facilities and growing facilities for citrus fruit?

DR. PARISH: I'm not knowledgeable--I do not know that there is any limitation on the placement of growing facilities for animals and citrus. The vast majority of groves that I'm aware of do not have fences around them and, to my knowledge, do not have cattle grazing in them.

I think that there are a couple of instances where that is correct that that can happen, and one of the issues that we have tried to push with the people that are producing fresh squeezed at all levels is that they have to make sure that the source of their oranges comes from groves that do not allow that to happen, first of all, do not have cattle grazing in the groves and do not use raw, non-composted manure for fertilizer, which does happen on occasion in Florida. There are some grove owners who do choose to use chicken manure, and we have asked the people who are producing fresh juice not to buy fruit from them. Whether they are or not, I don't know, but we have made that recommendation.

DR. STROBOS: Let me just clarify here a little bit because, you know, maybe it wasn't clear--oh, my name is Jur Strobos. The fruit that is used in the fresh juice operations that we're talking about is not going through packinghouse cold storage rooms. It's coming from the grove, you know, being sanitized by the companies, and then going into juice. So there's not a cold storage operation involved here in these particular operations.

MS. OLIVER: Bob, do you have any other questions?

DR. BUCHANAN: Well, I'd like the California perspective on the collocation or adjacent location of animal-rearing facilities and groves.

DR. ARPAIA: Like Dr. Parish, I can't categorically give you an answer. I can give you a generalization, though. We do have a fair number of poultry and livestock operations in the San Joaquin Valley where approximately now 60 percent of the--almost greater than 60 percent of the oranges are cultivated. However, they're geographically different. The citrus are predominantly grown on the east side of the San Joaquin Valley up in the foothills. Most of the feedlots and the poultry operations are on the west side of the San Joaquin Valley or out on the valley floor where it is too cold for citrus to be grown.

In the 16 years I've worked for the University of California and all the groves I've visited, I have never seen cattle or chickens or anything running through groves. But that doesn't mean it cannot occur, but to my knowledge, that is not practice. Most growers in California use clean cultivation and minimize any traffic through the groves for many, many reasons. Mainly it's because of liability, actually. If you have someone come and break a leg in your grove, of course, you're liable. So people are very cautious about having anything other than people who work for the operation in the grove.

MS. OLIVER: Alison?

DR. O'BRIEN: Yes--oh, he's not there.

MS. OLIVER: Can you identify yourself?

DR. O'BRIEN: Alison O'Brien, Uniformed Services. Dr. Strobos, a question for you.

I'm not going to ask you a microbiological question. It has do with the consortium that you talked about, you've been talking about representing, which is, as I understand it, four companies that try, from what you've

said--and it certainly sounds like it--try very hard to abide by all possible rules along the way. What I want to know is how representative are those four companies. How many other fresh squeezed companies are there, small or large, out there? And what kind of interaction does the consortium have with these other companies? What kind of peer pressure is there to conform to your standards?

DR. STROBOS: My understanding is that--first of all, I think actually, you know, we have Peter Chaires here from the American Fresh Juice Council, which is a little bit of a larger organization which does represent some of these other companies. But obviously I've had a number of conversations with companies outside the consortium, and my understanding is that these practices are not particularly difficult to follow and that they are being followed.

You know, I can't speak specifically to all of the particulars that you're addressing questions to, for instance, you know, the questions about livestock. I know that members of the consortium don't buy from groves that have livestock in their groves. Just as an example, I wouldn't know whether that would apply generally to all of the growers, but I do know that these kinds of communications from the University of Florida and from the Department of Citrus are generally picked up by the companies in general.

But let me see if Peter Chaires can speak more particularly about that.

MR. CHAIRES: Again, my name is Peter Chaires.

As far as sheer numbers, we don't have an exact handle on it. The volume of juice produced by the four members within that consortium group certainly is a considerable portion of the volume on unpasteurized juice that's produced in the country.

Within Florida, most of the--well, I'd say probably upwards of 95 percent of the fresh juice volume is produced by either members of the Florida Gift Fruit Shippers Association or the American Fresh Juice Council members that are within the state.

Now, in the smaller operations, when I refer to gift fruit shippers or roadside operations, about 98 of those are members of Florida Gift Fruit Shippers, and that's going to comprise a preponderance of the volume of the small operators. So we have about a hundred there, we have about 23 members of the American Fresh Juice Council that are scattered around the state, but that's broken up among vegetable, apple, and citrus.

But one thing that we have found, even though some of these larger operations obviously in volume and scale are different than what you would find and what we would call a non-continuous production facility or a roadside, the sharing of information and technology and techniques between small and large, we have found that most of the principles are transferable down to a small level, even if they may produce one, two, or three hours in the morning for that day's sales, and then go through their cleaning and sanitation procedures, shut down, and then juice again the next day. They're not a production plant like some of these larger facilities are.

The transfer of that knowledge and that technology through workshops that we've been able to put together through either the Department of Citrus, the University of

Florida, or a combination thereof have been pretty successful. And the small companies have been very willing to adopt to those technologies.

MS. OLIVER: We have one more person who wants to respond to your question and thinks might be able to clarify, too.

MR. BARNHORN: Brad Barnhorn from Fantasia Fresh Juice Company in Chicago.

Interestingly, there's not many fresh juice companies outside of Florida and California. It's mostly economic-driven; namely, it's--actually, it's a combination of economics and, ironically, product safety. The State of Florida will not let certain types of oranges be shipped outside the state. We can only receive in USDA grade 1 oranges. We can't get anything else out of the state. It won't be allowed by the inspectors.

So, ironically, being outside the state, just to answer the questions about Florida and California here, we are required to have basically store-quality fruit, which, like I said yesterday when I talked briefly, is what you would get at any major store chain.

So, to answer the question in terms of safety, A, in our prerequisite programs, we can't get fruit that isn't of the quality that is store quality.

Internally, we use an FMC extractor, to answer the question that was earlier put. We go through sorting, grading. We go through the microbial washes. We go through the whole same process. So it's--to be in this industry, like I said, we were born and began producing 14 months after the Odwalla incident. We had the opportunity to start from day one with a HACCP program. There are some things that we're fortunate being outside the state when we began operations that led us to incorporate into how we operate a lot of the safety protocols. So I don't know that there are juice companies outside Florida and California that exist, quite honestly, in the citrus side, but speaking for the one that does that I know of, we do follow their programs and similar safety protocols, and we are a member of the American Fresh Juice Council as well, so we're very well informed.

You know, 14 months before we began operations, we were at the meetings in December of '96 in Washington, so we--you know, a lot of that stuff has been built into how we operate.

MS. OLIVER: Thank you.

Alison, did you have any other--

DR. O'BRIEN: Actually, I did have a microbiological comment. A comment, not a question.

MS. OLIVER: Go ahead.

DR. O'BRIEN: It has to do with 0157 and testing, microbiological testing, or being sure that it's not there. Just to remind everyone that what six months ago was 3 percent of our cattle that has 0157, and now it's closer to, using better methods, 38 percent, maybe. I'm just saying that you get what you look for. And if methodology--and this goes back to Peggy Neill's question. We need to know, when we say it's not there, what methodology is being used, and it can change, sensitivity levels can change dramatically with methodology.

MS. OLIVER: Great. In response to that, when we take a break, I'm going to allow a half-hour break so that

people can get the answers to that question and compile it for the Committee for after it on the methodologies and sensitivities. And that goes to the importance of the question, too.

Okay, Roberta?

DR. MORALES: Yes.

MS. OLIVER: Please identify yourself.

DR. MORALES: Roberta Morales, Research Triangle Institute.

I'm actually glad that you are providing that time to get information on the testing, because yesterday when I posed that question, there was still some clarification needed. So that to me is another question that I would like to follow up on, and I'm looking forward to responses on that.

But I have another question that's more related to trying to understand the industry and what some of the constraints are, and this may be a question for Dr. Ismail or I guess somebody else, maybe Dr. Strobos. But in describing the outbreak and the recall, there have been several individuals who have said they think that this is--they believe this is a failure in the GMPs. What I'm trying to get a better understanding of is from the industry's perspective--and, you know, I can see that there's folks yesterday that said that they would like to maintain being able to provide the fresh squeezed juice and differentiate their product from the ones who deliver pasteurized.

What I'm curious is how would the industry have thought about how they might have modified GMPs or maybe improved the monitoring process, both in the past and maybe in the future, in order to minimize the potential for occurrence of outbreaks.

MS. SEXTON: You asked how would we regulate the industry so that this wouldn't happen again?

MS. OLIVER: And if you could identify yourself.

DR. MORALES: Actually, what I'm curious about is finding out what are the proposals that the industry thinks would be possible to minimize these things from occurring?

MS. SEXTON: I'm Mary Grace Sexton with the Orchid Island Juice Company.

What we proposed, and I'm the last person they wanted to get me to get behind this mike, but, you know, God is good to me.

What we would like is we would like governmental regulation. We have USDA continuous inspection. It works well for us. We want to implement HACCP, mandatory HACCP in the plants. HACCP and outside biological testing we think is very, very important. And as far as tests, we would like your input very, very much as to what procedure or test protocol you want us to use because we want the same results you want. So we would like mandatory HACCP in all programs, we would like mandatory USDA inspection on site continuously for processors, and I think you see--and as far as what we have, there is a great deal of peer pressure because the two people that got people sick have gone and stated publicly they want to go to pasteurized products because it's easier for them, but we don't want that. We'd rather have USDA continuous inspection, mandatory, and mandatory HACCP--countrywide, not just in Florida.

MS. OLIVER: Roberta, do you have other questions?

DR. MORALES: Yes. I guess I'm curious about how

continuous USDA inspection might be occurring and what are the components of that kind of a program? Does it include monitoring of the product at the final--where?

MS. SEXTON: The USDA inspector is on site continuously. They check the facility, they check the product, and then they have even become so sophisticated that they say everything has to be charted and graphed. They don't care. They want you to have a computer operator on there that can chart and graph all of your micro results so they can see the results in numbers and also in a graph to see any movement at all in your testing, in your biological testing, for your E. coli 0157, your Salmonella, your bacteria, everything.

MS. OLIVER: Any other questions, Roberta? Roberta, any other questions? Because we can come back to you later if you want.

DR. MORALES: Yes.

MS. OLIVER: Skip?

MR. SEWARD: Thank you. Skip Seward, McDonald's.

My question is regarding raw material specifications, and I'd just like to--I heard a little bit from the gentleman from Illinois about his restrictions, but my question is really whether or not there are regulations or standards that say that people who are going to squeeze fresh juice can only use choice or first-grade oranges or are you allowed, whether you are small or big, in any state to use any oranges you want to do fresh squeezed or can you use imported oranges?

MS. OLIVER: What I hear you asking is, one, there are no federal regulations that--we don't have any regulations that address that. What I hear you asking is are there any specific state regulations that restrict the type of orange that can be used in fresh juice.

MR. SEWARD: Correct.

MS. OLIVER: I do not know the answer. Mohamed, do you know that?

DR. ISMAIL: I don't know of any requirements.

MS. OLIVER: Okay. Fine.

Is that your only question, Skip?

MR. SEWARD: Yes.

MS. OLIVER: And can you identify yourself.

MR. MARLEA: I'm Dominic Marlea. I"m the director of Quality Assurance at California Day Fresh Foods.

As the committee looks forward to what they want to recommend, it's not just saying, okay, this is a HACCP rule that we want to put forth because anyone can say, "I have HACCP. This is a rule." But if they don't take HACCP, and they don't put it down all the way to the employees, back to the grower, the chances of really this being successful is going to be difficult. So the industry has to understand, when they take the HACCP under, as we're looking at it with the Florida regulation, they say you have to test here, test there. Also, they have to look at establishing standards.

In our company, what we do is we have specifications that are set forth. We hold the majority of our products from the groves. I go out and deal with the growers, look to see and make sure that, in no way, livestock is around these groves. Sure, you're going to have a deer that's going to run through the orchard. You can't stop that. But these things have to be looked at by

those companies, and it's the company who has the responsibility to say this is what we want to do if we're going to produce fresh juice; if not, then that company shouldn't be allowed to make fresh juice.

MS. OLIVER: Michael Groves, next.

I want to remind the people that what we're doing is trying to ask questions of clarification and just answer the specific questions from the committee.

MR. GROVES: Mike Groves. I'd like to ask Dr. Pao a question.

We've had a lot of discussion about the Dr. Strobos data on the surface of oranges. And you gave some data about yours, and it seems that you got a 2-log reduction, and you macerated the oranges and counted them, and then you said you put it in a commercial extractor; is that right?

DR. PAO: Yes.

MR. GROVES: And you got a 2-log reduction; is that true?

DR. PAO: Yes. I'm Steven Pao.

MR. GROVES: The methodology there was different. You macerated the whole orange and counted it afterwards.

MS. OLIVER: Can you identify yourself, please.

DR. PAO: Steven Pao.

At the same time we did a surface count based on shaking six fruits in a sterile bag, and the count was near identical. The difference between macerated juice count and bag shaked surface count is less than a half-log difference.

MR. GROVES: Right. Okay.

I wanted to ask Dr. Miller a question. It seemed to me that there was a discussion about removing buttons from oranges so that they were all alike; is that right?

DR. MILLER: This is Art Miller.

That is true.

MR. GROVES: And we'd heard some information earlier concerning dropped oranges, how could you tell the difference between a dropped orange and nondropped or freshly picked is by looking at the button, and there was a scarring that took place. Do you have any thoughts that the absorption of a pathogen or dye in a freshly debuttoned orange would be any different from one that had not had the button taken off of it or did you test that?

DR. MILLER: We didn't test it, and I certainly don't claim to be an expert in this area, but I think intuitively what you are really talking about, in our case, was that these were oranges that had been through commercial sorting processing and then shipping. So you are talking about time, and one of the things that we noticed when we took them out of the cases that you do see some buttons. So I think they just dry up.

Now, again, intuitively, I would think you're changing the morphology and physiology of the superficial structures when you lose those buttons. So, I mean, you can speculate all you want, but I think we need to really think about this carefully. But I think an important point is that the stem scar is the most vulnerable part of the orange, so that's where the action is.

MS. OLIVER: Mike Jahncke?

DR. JAHNCKE: Mike Jahncke, Virginia Tech.

I have a--

DR. ARPAIA: I'm certainly not the authority to

get up here and make a comment--

MS. OLIVER: Can you identify yourself.

DR. ARPAIA: Mary Lou Arpaia, University of California.

I'm not the authority to get up here and talk, but there has been a lot of work done on wound healing that occurs in citrus. And there is a wealth of literature both from Florida, California and Israel showing that lignification occurs when the fruit are wounded and the fruit are subsequently held. And I think that also has to be considered in this removal of the stem scar; that lignification does occur and that work that Dr. Eckert and I conducted, and I don't have the data with me so I can't provide it, but we did look at the incidence of the Alternaria stem-end rot in lemons that were harvested without stems versus the buttons that fell off during storage, and there is a difference, and it can be linked back most likely to this wound-healing phenomena.

DR. TOMPKIN: Before you leave, I want clarification. This is Bruce Tompkin.

Does the wound healing occur on the tree or are you talking about after picking?

DR. ARPAIA: After harvest.

There's certain post-harvest treatments, actually, that stimulate wound healing, and a lot of work that's been done in Israel at the Volkani Institute regarding wound healing.

DR. JAHNCKE: Thank you. Mike Jahncke, Virginia Tech. Dr. Arpaia, this question will be directed to you.

I know there are diff--yesterday and today--there are differences between some of the procedures that take place in Florida versus in California. If I heard correctly, I believe in Florida there is no immersion of any of the fruit that's used for fresh juice, and I believe that it doesn't go through a packing house, but it goes from the groves directly to the company.

Yesterday on your slides, you showed a slide, I believe, at a packing house where some of the citrus was in immersion. It was immersed in water.

DR. ARPAIA: Correct.

DR. JAHNCKE: And then you had also indicated that there are occasions where that fruit that is immersed in that water has been used for fresh juice.

DR. ARPAIA: That is correct. As I indicated, about 30 percent of the orange houses in California have these tanks. The tanks, there's been a lot of research done most recently by Dr. Smilonek, who works for USDA in Fresno, on the efficacy of these tank treatments for decay control. The tanks are never just chlorinated water. They always have either soda ash, sodium bicarbonate or somehow--we have two houses using borax, boric acid or we have a new fungicide registration that Dr. Smilonek worked on, which is lime sulfur. So there's always one of those four chemicals going to be in that tank treatment. Most likely it will be either sodium carbonate or sodium bicarbonate.

The maximum immersion time, because you want to minimize fruit damage, is not going to exceed 3 minutes, but the average is 1.5 to 2 minutes. In the case of borax, boric acid and the soda ash, the tanks are heated to approximately 105 degrees. As Mr. Orman indicated, that can range from 90 to 110 degrees Fahrenheit. but those tanks

are always heated. When you use sodium bicarbonate or lime sulphur, then you are using ambient water conditions. But, again, that's going to be 65-, 80-degree Fahrenheit water.

DR. JAHNCKE: Okay. That gets to my point, especially with the sodium bicarbonate. I think yesterday it was indicated the pH is around 8, 8.5, something like that with the sodium bicarbonate.

DR. ARPAIA: Correct.

DR. JAHNCKE: And you have 70- to 80-degree water, and you had indicated this morning that some of the fruit, during the year, has also been picked and comes in that I don't know 45 degrees, perhaps.

DR. ARPAIA: But they don't like to, they won't dump the fruit on the line when it's 45 degrees because that fruit is turgid and very susceptible to damage. So you want to run the fruit warm. And the minimum pulp temperature they like to run the fruit at over the line would be 50/55 degrees. By the time it reaches the tank, it's already been on the line maybe two/three minutes. It's gone through one to two chlorinated water rinses already before it hits the tank.

And, again, they take a lot of care here because they know that if they run cold fruit through a heated tank, you get a lot of rind damage. And so, you know, everything is geared towards we are a cosmetic industry, and you want to do everything possible to minimize cosmetic blemishes to the fruit.

DR. JAHNCKE: But it is possible that fruits coming in at 50-55 goes into a tank of 70- to 80-degree water?

DR. ARPAIA: It's possible, yes.

DR. JAHNCKE: And you had indicated yesterday also that that tank water is changed once a week, maybe even twice a week?

DR. ARPAIA: No. I was told, on the average, it's changed every one to two weeks. But, typically, in the houses that have boilers, that those tanks are heated up to 140 degrees every night.

DR. JAHNCKE: To your knowledge, has there been any--there's been a lot of talk as far as the process, and good GNPs and all of these things, and it also gets back with the tank immersion and also even with the reuse of some of the water in the sprays and the brushes. Have any of the companies collected any data as far as microbiological bacteria, the bacteria present in those tanks or in the wash or is there is any count, you know, looking at numbers and types of bacteria, as far as concentrations?

DR. ARPAIA: For human pathogens?

DR. JAHNCKE: Correct.

DR. ARPAIA: Not to my knowledge, but it could very well have happened, but not to my knowledge. I haven't ever heard any of that data.

DR. JAHNCKE: One last question. The question was passed down.

The fruit that comes out of a packing house when it goes to a fresh juice processor, is it--and I believe the previous speaker indicated that that fruit is usually rewashed at the fresh juice place; is that correct? Is that a correct assumption?

DR. ARPAIA: I would assume so, but I cannot categorically answer that question.

DR. JAHNCKE: Thank you.

MS. OLIVER: Since Dr. Arpaia is at the mike, and before she sits down, and before we go to break, did anyone else have a question for Dr. Arpaia?

Larry?

DR. BEUCHAT: Are the orange groves--

MS. OLIVER: Can you identify yourself.

DR. BEUCHAT: Excuse me. Larry Beuchat, University of Georgia.

Are the orange groves in the San Joaquin Valley irrigated?

DR. ARPAIA: Oh, we have to irrigate. We're a 100-percent irrigated industry. We just had a meeting just recently, and the estimate now is 100 percent of the groves in the San Joaquin Valley are under some form of low-volume irrigation. There is no longer any grove that I can think of that would be under flood irrigation. There may be one or two still under furrow irrigation, but we are approaching 100 percent of the groves will be under some kind of low-volume sprinkler or drip irrigation system.

In Southern California, it would be 100 percent. Because of the cost of irrigation water, it is just not cost-effective to be doing flood or furrow irrigation any longer.

DR. BEUCHAT: What is the source of the water?

DR. ARPAIA: The source of the water varies throughout the state. In the San Joaquin Valley it's mainly Sierra snow melt water. There is some well water being used.

DR. BEUCHAT: Are the livestock areas upstream or downstream from the citrus-growing and irrigated areas?

DR. ARPAIA: They would be downstream because the livestock and the poultry are down on the valley floor. The citrus are grown up in the foothills at a slightly higher elevation. We have very strict, and I'm not an authority, but we do have some very strict groundwater quality legislation in California on water quality, et cetera. But in the San Joaquin Valley, the bulk of the irrigation water is going to be Sierra Mountain snow melt water.

DR. BEUCHAT: So that runoff water from the livestock growing areas would be diverted to other purposes and directions. It would not be used in irrigation water for the citrus groves?

DR. ARPAIA: As far as I know of, no, but if you want, I can make some phone calls and get clarification for that.

DR. BEUCHAT: One last question also on the San Joaquin Valley. What is the predominant direction of the air flow, wind, relative to the livestock growing areas versus the citrus growing areas?

DR. ARPAIA: That's a good question. It depends on what time of year. Sometimes the wind comes from the west, sometimes it comes from the north. I would say predominantly, I'm trying to think, because we published a paper on a Valencia rind stain, and we had to answer that question in the review. And I looked at three years of data, and the predominant wind direction was from the northeast, which would be then not coming from where the livestock would predominantly be located. But I will call, and if I have a different answer, I will call and have someone look at that manuscript. And if it's a different

answer, I'll let you know.

DR. BEUCHAT: Thank you.

MS. OLIVER: We'd like to go to break now, and we'll have a half an hour break so that industry and others can gather the data on the test sensitivity.

Did you have something that was particularly addressed to the question?

MS. GIRAND: I spoke with Jeff--

MS. OLIVER: Can you identify yourself.

MS. GIRAND: Laurie Girand, Safe Tables Our Priority.

I spoke with Jeff Ferraro [ph.] last week about--actually, last month, about irrigation water issues, and he indicated that Coachella Valley was, in fact, irrigated with water from the Colorado River and that it hadn't particularly been tested to any particular quality levels and that we have in California right now a water recycling rule that's under consideration which would allow for the use of largely untreated wastewater on crops. So water quality isn't quite what it might be.

MS. OLIVER: Thank you.

MS. NAGLE: Nancy Nagle, Nagle Resources.

Yes, canal water and Colorado River water is used extensively in the southern part of the state. Primus labs has an extensive database on this water and has shown, out of thousands of samples, very few positive E. coli results for this water. I think we can go to their database and check that out, perhaps, during the break. And some of the recycled water issues I think we could talk about extensively later. But I have a lot of information in that.

MS. OLIVER: Okay. Fine. So, if we can get that at break time, and we'll also get the information for you on the sensitivity.

And so we'll come back at about 25 after. Thank you.

[Recess from 9:55 a.m. to 10:35 a.m.]

MS. OLIVER: The first thing I'd like to do is just mention that we handed out this morning the statement from CSPI. They were not able to be here yesterday for the public comment, and so they have a statement that's here in your packet, and they are represented here by Darren Mitchell is here today. So I want to call your attention to it so that you can look at that this morning and take that into consideration, also.

The next thing I'd like to do is say that there are a number of you that still have questions. And what I'd like to do is plan on going until noonish or lunchtime with questions of clarification that you all have. Around noon or so what I'll do is if there are people that still have questions, ask those who think they have questions that are critical to your deliberations in the afternoon, for those to be the ones that are asked at that point, but it'll give you plenty of opportunity.

I gave a little extra time because people were still working on sensitivity of method and answering method questions for you all, and some of you gave questions that you wanted specifically answered, and they were being responded to. So we have that lined up.

Then, after lunch, what we'll do is we'll have the committee discussion, and we'll proceed from there. And I'll poll the committee sometime in the afternoon. I don't

have an exact ending time. I just want to make sure that if you think there are questions that are critical to your deliberations, that you have the opportunity to ask that and do have opportunity for discussion.

So Art Miller is going to discuss FDA's lab procedures and sensitivity, and I believe Dr. Parish is going to discuss, from the standpoint of the industry, the sensitivity and methods that are being used, and then you can ask questions of them both.

DR. MILLER: Sensitivity has arisen, and this transparency was alluded to yesterday. My name is Art Miller, by the way.

The question came up about sensitivity and methods of choice. And as it was brought out yesterday, that there were questions about the sensitivity and the ability of the Salmonella method that was used in the BAM, which included a step to use lactose broth as a pre-enrichment and to address this question. This is work by Tom Hammack and Wally Andrews. And I want to say that it was very recently presented at an international food microbiology meeting in the Netherlands just a few months back. This work is now being finalized for publication. It is the method that we are recommending and have been making this information publicly known.

What these investigators did was take three different Salmonella serovars, prepare stationary phase cultures and then dilute out to extinction, and the data that you are looking at shows the ability to recover the Salmonella at a range of three in a liter up to 231 organisms per liter using the traditional lactose broth for pre-enrichment versus the universal pre-enrichment broth, which was developed the ARS Laboratory in Athens, Georgia.

And of a total of 120--a possibility of 120 replicates, and I've really extracted this, the lactose broth was able to recover 44 percent, and that's across this whole range, versus 81 percent for the universal pre-enrichment.

Of course, we need to bear in mind that, as you start diluting down to extinction, you are really playing the shell game because not every one of those 20 replicates will contain Salmonella. So it's very, very difficult to say where that cut-off point is. But in this instance, we were looking at three organisms in a liter of--a concentration of three organisms in a liter of material.

MS. OLIVER: Art, did you want to say when this was done and when the method was, we were changing it?

DR. MILLER: The research was done over the course of the past couple of years. It has been finalized in our laboratories. As I mentioned, it was presented this fall at an international meeting in the Netherlands and Europe. It is going to be published. We've been recommending this to all interested parties, and this is an orange juice, I should mention at the beginning, it's orange juice specific. And as most of you are aware, to really squeeze out the most sensitivity for any method, there have to be modifications made. You can't just blindly go in and apply a method and say this is the ultimate insensitivity. So it took a lot of effort to get us this far.

We've recommended it to all of our field labs, to the states, to the industry, and we're trying to get the word out to as many people as possible that this is the

method of choice.

DR. BERNARD: Just for clarification--Dane Bernard NFPA.

For clarification, how many mls did you sample? You had three organisms per liter?

DR. MILLER: Yes. What they did it was an MPN type so they grow up the culture and then fractionated it and did MPNs.

DR. BERNARD: What was the sample size, though on Salmonella?

DR. TOMPKIN: How much was pre-enriched?

DR. MILLER: Right. I don't have that. I can--I actually have the notes, and I can inspect that. I didn't bring it up with me.

MS. OLIVER: If you can check that then when, you know, the next presenter, and then come back with that.

John?

DR. KVENBERG: Thank you. John Kvenberg, FDA.

I think, if I can just discuss, Dane, what you are I think going for is the standard BAM procedure for a finished food would be a composite sample of 30 for a food that's radiated versus 15 for a raw commodity. I think for the recommendation of the method of the BAM procedure, that'll be the sampling size aliquot that we're going to be involving; is that true? The methodology itself would require, as it does in the BAM, that remains unchanged for a food that's ready to eat.

DR. MILLER: Yeah. The modification is the substitution of the universal pre-enrichment for the lactose broth.

DR. KVENBERG: I don't know if that went to Dane's question or not, but that I think is the point relative to the application of the methodology for the finished juice would be the standard BAM procedure for Salmonella doesn't change.

DR. MILLER: Right.

DR. KVENBERG: Thank you.

MS. OLIVER: Dane, does that answer your question?

DR. BERNARD: It does. If I have a chance to look at the BAM, I'm sure I can get my answer. Thank you.

MS. OLIVER: Art can look it up and give you that answer in between.

DR. MILLER: Any other questions of clarification?

MS. OLIVER: Yes, any other questions of clarification for Art?

Okay.

DR. PARISH: I'm Mickey Parish, University of Florida, and I have just spent the last several minutes discussing procedures that are used by the consortium of the four companies, the two California and two Florida companies and their testing procedures. So this is very fresh in my mind, and hopefully I won't make too many errors.

It's obvious that at the four companies they do things a little differently. They have different sampling procedures and different test methods. And let me begin by saying basically the California companies do testing by pulling a sample from a tank so they test the tanks themselves. The tank sizes range anywhere from 3- to 7,000 gallons.

This amplifies, as I understand it, when it's pulled, can range from 100 mls. to roughly 8 ounces of that.

That is--of that sample, then 25 mls. is pulled and is run through a standard procedure for pathogen testing. The Florida companies did the same thing for tankage, and they also do end-product testing. Two of the companies do their pathogen testing in-house, two of the companies send their samples out.

The samples are pulled--when they pull the samples out of the tanks or out of the bottles, they are refrigerated at the time and they are maintained under refrigeration or packed on ice so that they are cold. The ones that ship the samples out, the samples arrive--the samples are normally pulled during the day, shipped at the end of the day, and arrive at the lab the next day. So there's roughly a maximum of about 24 hours before the samples are begun tested. The in-house folks say within two to four hours of their samples, they begin testing of their samples.

For the Salmonella testing, there are two methods that are used. One is an ELISA method by Tecra [ph.], called the Tecra Unique System. It is under AOAC review and will--should be approved by--they are anticipating AOAC approval within a few days--within a few months. That test takes roughly 24 hours if it's in-house and 36 to 48 hours if it's sent out. The other--one of the four uses the BAM method. They send it out to an outside lab, and the person at that lab has indicated that it takes her five days to get results.

The E. coli 0157 testing that's done, two of the companies use something called a VIP method, which has AOAC approval, VIP method from Bio-control. It's a visual immuno precipitate method. It has an AOAC official method approval number.

One company uses a clinical test that is under review for testing in foods. The VIP has a turnaround time if it's in-house--well, the VIP has a turnaround time in-house of roughly 18 hours; if it's sent out, roughly 36 hours. The other clinical testing method is in about 8 hours.

The fourth company for 0157 uses a compendium method, and that method again takes roughly 5 days. The person at the lab reports the Salmonella and 0157 results back to the company on the same day.

These samples, again, are 25 mls. in size. The Salmonella testing at one company is a 50-ml sample in size. They are reported as positive or negative. They have all been negative up to this point. And if we assume a 25-ml sample, I'm assuming that perhaps we can say that it's less than one cell per 25 ml, making that assumption.

The Salmonella Tecra Unique has been tested on 42 different serovars, and the--one of the companies involved has contracted an outside lab to verify both the Tecra and VIP testing for orange juice specifically, so they will begin the process of verification very soon.

That's all the information I have, hopefully.

DR. TOMPKIN: Of course we didn't ask the question before, but on the E. coli analysis, which looking through the information, I got the impression that at least one company was analyzing--this is Bruce Tompkin--analyzing a 10-ml sample for E. coli; is that correct? Are they 1-ml or 10-mls. for E. coli, because we had a lot of negative results?

DR. PARISH: I'm not sure what results you're referring to, what company you're referring to, Bruce, and is that generic E. coli or pathogen?

DR. TOMPKIN: Generic E. coli as part of the State of Florida requirement for end-product testing.

DR. PARISH: I do not know the answer to that. I believe some of the smaller plants may actually use the 3-M petri film method for detection of E. coli, so in those plants the detection limit would be something in the range of 1 per ml. The others I don't know. I think some of them may actually use a traditional test method as in the compendium, which I believe that's 1 per 10 or 1 per 25.

Yes, Bob?

DR. BUCHANAN: Bob Buchanan, FDA.

Are positive controls run with all of these analyses?

DR. PARISH: That's a good question, Bob, and I don't have an answer for you. I assume that--I would assume that they are not if they're run in-house, if they're pathogens, because I don't think any of the plants will handle pathogens in-house.

MR. MARLEA: On ours a positive controls method, positive/negative.

DR. PARISH: Okay. So at least one of the companies does run positive/negative controls on their testing.

DR. KING: The VIP and the tec method both.

DR. PARISH: Okay, two companies do.

DR. KING: The VIP and the tec method both [off mike] positive controls.

DR. SWAMINATHAN: You mentioned one of the companies runs a clinical method that takes 8 hours. I'm very concerned about it because clinical specimens are very different from foods in terms of the numbers of organisms that you're likely to find in 8 hours bothers me. Can you give me some more details?

DR. PARISH: I cannot give you more details. Unfortunately, that's as much as I know, and I share your concern. I think that that test method, they--it's my understanding that test method is being reviewed for food by the company that makes the test. It is a clinical test at this point, and I share your concern that perhaps that's not the most appropriate method to use.

MS. OLIVER: Dane?

DR. BERNARD: Thanks, Dane Bernard.

Is there any reason to believe that we have a homogeneity problem with say a tank of juice in terms of distribution of organisms?

DR. PARISH: The tanks are all agitated, so to the best of their ability, the tanks, we would assume the sample is homogenous, yeah.

DR. KVENBERG: John Kvenberg, Food and Drug Administration.

I think, just for clarification purposes, on the actual drawing of samples for the methodology, is it not correct that you're basically down to an analytical unit of, I believe, 25 grams?

Going back to Dane Bernard's comment, the full utilization of the sampling procedure for ready-to-eat food would be aliquots that are composited for enrichment. In other words, 25-gram samples would be composited into a

total of 750 mls. of product in two enrichment broths of 375, 15 each, for convenience. That's not normal industry practice, and I just don't want to leave the impression that that's what's being done here. There are individual aliquots of perhaps 25 grams being run by the procedure that represent that batch. It's not a combination of the lot.

In other words, if you had--you would be pulling samples from actually 30 points and compositing them and enriching them in a full BAM procedure. That's not being done.

DR. PARISH: That's correct. That's correct. There is one company that is compositing their samples. They pull--however, they pull one sample from 6 different tanks, then composite those samples from 6 different tanks, but that's correct, they're not compositing from an individual tank.

MS. OLIVER: Any other questions or clarifications on the methodology?

DR. DOYLE: Mike Doyle, University of Georgia.

How many of these assays that you are using have truly been evaluated in terms of determining the sensitivity of the test for orange juice?

DR. PARISH: As I said, the Tecra and VIP methods have been--are being contracted, companies contracting to do that with an outside lab. To my knowledge, they have not been specifically looked at for orange juice. I believe the universal pre-enrichment broth type system for Salmonella, as Art just indicated, is a desirable methodology, and for the folks who are doing the modified BAM procedure, I make the assumption that that's what they're doing. I don't know that that's true.

DR. DOYLE: And has any effort been made to validate procedures? That is, Dane brought up the point of sample testing. How good is a 25-ml sample or up to an 8-ounce sample from a several thousand gallon batch?

DR. PARISH: I'm unaware of anything that's been done to validate the adequacy, but perhaps Jur can--

DR. STROBOS: My understanding is that there has been some validation done in acid foods, but not specifically in orange juice. You know, let me be clear here. We are certainly seeking the input of this Committee in terms of what kind of comments and improvements we can make in this process, and that's part of the reason we're here.

DR. DOORES: This is Stephanie Doores, Penn State University. Mickey, what procedure is used for the generic E. coli?

DR. PARISH: Again, Stephanie, I'm not exactly sure. It's my understanding some of the smaller companies may use the 3-M petri film method. Other companies may use the compendium method, which would be an enrichment.

DR. DOORES: You mean the most probable number method?

DR. PARISH: MPN, yeah.

DR. DOORES: Does anyone use the standard agar plating with violet red bio-agar?

DR. PARISH: I have no idea. I don't know, Stephanie.

DR. DOORES: One of the concerns with the petri film may be with the volume that's used to perform that test. You might have some situations where the pH is still

fairly low on that agar to the point where you may not get visualization of those organisms, where in something like an MPN or even an agar plating procedure, you may have dilution of that orange juice to the point where the buffering capacity allows for a more neutral recovery environment, so I could see where there might be a possibility that you get positives in those types of tests but potentially negatives in the petri-film type of test.

DR. PARISH: I share your concerns. I've wondered about petri film in the past. And I know that some companies do, at least early--years ago, when they were first investigating petri film for E. coli in orange juice, some companies were diluting 1 to 10, therefore sacrificing some sensitivity in order to try to balance the pH issue.

MS. OLIVER: Mike?

DR. JAHNCKE: Mike Jahncke, Virginia Tech.

I have a question that relates to John's and Dane's question on sampling and delivery of the sampling and things. In the Florida guidelines there are, on sampling rates there are a recommended number of samples for the size of the containers. I was just wondering--it sounded from your presentation now that this isn't necessarily being followed, and I was wondering why.

DR. PARISH: Well, I think that's a very good question, Mike. I would wonder why also. I don't know what the sampling recommendations are in the regulation, in the Florida regulation. I think that the companies involved should make sure that they are meeting that regulation and that's really all I can say to address that.

MS. OLIVER: Any more questions or clarification on the methodologies? I don't see any more. Okay. Thank you.

With that, we'll continue on the questions that we started before. And, Dane, you have a chance to ask your question.

DR. BERNARD: Thank you, Madam Chairman. Dane Bernard.

A question for Dr. Pao. I think he's still here.

MS. OLIVER: He's right behind you.

DR. BERNARD: It relates to the discussion we had yesterday about the dipping in the orange, putting it into the extraction device, and getting juice and a number of organisms in the juice. And if I remember our discussion yesterday, we had 105 roughly, and there was Bill Sperber's concern this morning about translating a surface enumeration into a volumetric enumeration of the product. But all that aside, we had microorganisms on the surface of the orange, and we had some less--I think you said a 2-log reduction. I wouldn't necessarily call it a reduction. I would say it didn't transfer into the juice, but we left 99 percent of them in the extractor or it went out with the peel or whatever. And the 1 percent that came through in the juice, do you have an idea of how that happened, where those organisms may have been and how they ended up in the juice?

DR. PAO: My name is Steven Pao. And in my slide, where I show the bars, the first bars are control. That's based on macerated juice count, so that was not surface count. Based on--the macerated juice count represent, I believe, the inoculation level on the fruit surface. From that macerated juice count to our control juice, from the extracted juice, and we see 1.9-log reduction, so it's from

juice to juice we have 1.9-log reduction. And if you say why there are some in the juice, see, in the juice extraction method alone we not achieve that low a reduction.

Juice extraction technique, commercial juice extraction, we have--in Department of Citrus we have conduct 30 on at least three companies' juice extractor. We found, consistently found reduction through their juice extraction. But I guarantee you there is no 5-log reduction by juice extraction alone.

DR. BERNARD: I understand that. I was just trying to understand. I think the material we were supplied, we had a schematic diagram of the FMC extraction device, and it talked about cutting plugs, and juice would be extracted around at least the bottom plug. Is that the same device or the same function that you used, and could the 1 percent that was transferred into the juice have been on a little bit of that plug that gets contact with the juice?

DR. PAO: Right. There are certain contacts between--otherwise, the blades would not enter the fruit. So the reason I demonstrate that in the meeting is I want to use that as my control to compare to a treatment such as hot-water treatment can give you 5-log reduction.

DR. BERNARD: Okay, thank you.

DR. PAO: You're welcome.

MS. OLIVER: Dr. Parish had something to add, Dane, to that question.

DR. PARISH: Mickey Parish. If I could just elaborate just a moment.

I think the reason that you were seeing some of the transfer is due to the plug, and that there is a minimal amount of juice-to-peel contact. According to FMC documentation that I've heard of, perhaps as much as 3 percent of the peel has the potential to come in contact with the juice during the extraction method, so that may be where we're seeing the organisms come that had been on the outside of the fruit, and again, unlike apple juice where there is intimate contact between the peel, the milled apples where the peel is mixed in with the pulp and is pressed, where there's intimate contact, in orange juice we want to make sure that there is very minimal contact with the peel for just a very small amount of time, because of the fact--for flavor issues, the peel oil has a tendency to make the juice very--gives you a burning sensation, so it's an organoleptic reason.

MS. OLIVER: Bill.

DR. SPERBER: Thank you. I'm Bill Sperber from Cargill.

My question is centered on the FMC extractors, and to some extent it's already been answered, but I want to pose my question maybe more for the information of the Committee, as we deliberate this afternoon.

Three years ago the citrus--fresh citrus producers were arguing that they shouldn't be lumped together with apple producers because they were different. Whole apples were macerated, and any external contamination could end up in the juice. They were different. Citrus is different because of the extraction process. There's not intimate contact between the peel and the juice, and so therefore fresh orange juice is cleaner.

So my question is centered on the FMC extractors,

that in fact, when you put an orange through such an extractor, you get four streams coming out. One is the juice. The second big stream is the peel that generally goes to animal feed. But the other two factions concern me, and that is one is the peel oil. In the FMC extractor there's a small water spray that washes--coves the surface of the peel and helps extract the oil. That's recovered separately. And then the core of the orange is cut out during the extractor, and in conventional orange juice processing, where the juice is pasteurized or concentrated, both the peel oil and the core are kept and further processed, and they end up back in the orange juice somewhere down the stream.

So I was thinking that if the fresh producers are trying to claim that their juice is cleaner because they don't have contact with the peel or even you could argue that if there are infiltrations through the stem scar into the core of the orange, that that too would be removed. My question for the fresh juice processors is what do you do with the peel oil and the core?

I had one answer from Ms. Sexton from Orchid Island during the break, but I wonder--she said that they don't use it, they completely throw it out. Is that true for the entire industry?

DR. STROBOS: Yes. This is Jur Strobos. The core and the peel oil is not at any point in contact with the juice.

DR. SPERBER: So just that mechanical fact of extraction would indeed differentiate fresh citrus juice from fresh apple juice in terms of potential contamination?

DR. STROBOS: Yes. Well, yeah, and I think, you know, just to reiterate Dr. Parish's point too. I mean, when you crush an apple, you crush the skin with the apple, and then the entire mixture is sort of mixed up, so there is intimate contact between the peel and the juice until some straining operation takes place.

DR. SPERBER: FMC claimed a 3 percent contact with the peel and the juice. In my experience, commercial extractors, each contain six heads, and one extracting unit will process over 500 oranges a minutes, so you end up with quite a mess. It looks kind of messy. And I'm just wondering if there's--if the fresh producers operate their machines that fast, as fast as the conventional producers? Do you have any idea of your line speed?

DR. STROBOS: I don't know the answer to how fast they run the machines, but I don't think--I mean, I've seen them in operation, and I dispute the description of it as being a mess. You know, the oranges enter the machines and the juice comes out in a contained system, and the way the machine works, you know, the peel and the other materials come out in a different system.

DR. SPERBER: You have to take the cover off to look on the inside to see what's going on.

DR. STROBOS: Well, if you open the machines in the middle of the processing, which you don't do, but the oranges are basically annealed to the surface of these. I mean, there are pins that come down and grab the orange, and the surface is annealed as the juice is extracted.

But let me defer to--

MS. OLIVER: Yes. There are two processors standing behind, so let's see if they have the answers.

MS. SEXTON: No. FMC had different settings on their machines.

MS. OLIVER: Please identify yourself.

MS. SEXTON: I'm sorry. MaryGrace Sexton, Orchid Island Juice Company.

FMC is technical enough that they have different settings on their machines. They also have machines considered a soft squeeze machine, meaning we don't want the peel oil in there, and that we do--a fresh-squeeze processor will run lots slower than a commercial pasteurized company. We run much, much slower.

And also when they go to say that they put the three--the razor on that orange and that's the contact point, I want to reiterate that orange has already received a 6.7-log reduction before that razor. So that razor is continuously sanitized by those byproducts that come with that orange, the sanitizer on the outside of the orange before that razor hits that orange.

MR. BARNHORN: Brad Barnhorn, Fantasia.

Just to confirm what MaryGrace said, we run much slower than that. I mean, on the first question, if I can, about the peel oil and the peel. Most of us here are--I think probably everybody--are fresh juice companies more than orange processing companies, so we're not looking to create byproducts. Everything that comes out that's not orange juice is thrown out by us.

DR. SPERBER: So you throw out the core too?

MR. BARNHORN: Yes, everything--the only thing that we maintain is the juice, everything else is thrown out as waste.

DR. SPERBER: Thank you.

MS. OLIVER: Earl?

DR. LONG: Earl Long, CDC. I have a question on orange anatomy and physiology. I don't know whether Dr. Pao would want to answer that. There are two questions. The first one is: do fluids enter oranges through continuously open channels in the vascular bundles or through pores in contiguous cells or through cell cytoplasm?

The other one is: do citrus oils have any inhibitory effect on microbes?

DR. PAO: From what I can remember, peel oil does have antimicrobial property. But how effective is that in this case, there's no direct study.

DR. LONG: I'll tell you why I ask that. Because I'm concerned that there may be a temporary inhibitory effect on bacteria that early sampling of the juice would not show the potential for later growth of microbes there.

DR. PAO: Did I answer all your questions?

DR. LONG: No, that's one. The first question was how do fluids enter the fruit itself from the plant?

DR. PAO: On the tree.

DR. LONG: No. I'm talking about the vascular bundle now. Is there a continuously open channel?

DR. PAO: There are--they call it a pit wall in the vascular bundle. At this time I talk to our electron microscope technician, and he's also our associate scientist. He said there are pit wall in the vascular bundles, so--

DR. LONG: So fluid will--

DR. PAO: --will stopped at the top. That's why we see lumps.

DR. LONG: So there are pores in the cell walls?

DR. PAO: There are walls.

DR. LONG: I'm asking whether there are pores in contiguous cells.

DR. PAO: Maybe a fruit person could--I'm a food technologist. Maybe a plant person can help me. Thanks.

DR. LONG: I'm just wondering whether there is some mechanism in the cells that could filter bacteria out or whether bacteria could just flow through channels?

MS. OLIVER: Dr. Arpaia, can you answer that?

DR. ARPAIA: Mary Lu Arpaia. You're asking a question on whether the vascular bundles--the vascular system remains functional after the fruit is harvested?

DR. LONG: I wasn't asking that, but yes, I'd like to know that.

[Laughter.]

DR. ARPAIA: Well, I mean when the fruit is on the tree, definitely, water goes into the fruit through the vascular system, and there's a lot of data showing how the fruit shrinks and expands during the day, depending on the water requirements of the tree.

DR. LONG: But does the structure of the vascular bundle act as a filter that could prevent bacteria entering the fruit?

DR. ARPAIA: To my knowledge, I don't think anybody has ever, ever really looked at that, but the vascular system in the fruit, from what I remember from reading the literature--and this is a while back--is that it's a typical plant vascular system. It does not have any specialized cells or cells that are different than the vascular system in the remainder of the plant. So it would have the tracheid cells and cells that are typically found in vascular tissue.

MS. OLIVER: Dr. Parish, did you want to add to that?

DR. PARISH: Mickey Parish, University of Florida.

And I'm not a fruit physiologist either, and I'm just going to make a stab at this. We have experts at the research center in Lake Alfred, who study these issues, and I'm sure would be glad to comment to your question. Regarding is the vascular system functional after harvesting, I asked that question specifically of one of our researchers. He indicated that upon pulling the fruit from the stem, that there is a break that occurs internally just beneath the surface of the stem scar that essentially breaks what he calls the water column. And, frankly, I don't know exactly what that means other than to say that the implication is that you don't get continuous suction or a forced pulling down completely down into the fruit, but it does stop at some point. That was my understanding of that conversation.

Is there a filter? There are pit walls. You have a tube of cells that come down and there are pit walls in between them. The fluid can flow through the vascular bundle, and we have seen, through some of the recent photo micrographs that the bacteria do--if they enter the vascular bundle at all, they tend to accumulate at this--will accumulate at a pit wall. So obviously there is some filtration effect occurring.

DR. BUCHANAN: Janice, can I--

MS. OLIVER: Bob.

DR. BUCHANAN: I attempted to do a little reading on fruit physiology before this meeting, and it appears that--

MS. OLIVER: Could you identify yourself?

DR. BUCHANAN: Bob Buchanan. It's still the same one.

[Laughter.]

DR. BUCHANAN: Citrus, like other fruits, when picked, at the stem scar region there is a response where there is a plug that's established that tends to seal off the vascular system. Once beyond that plug, as far as I could determine, the vascular system remains intact. If there is a sufficient pressure differential between the inside and the outside of the fruit, that plug can be overcome, and then once that plug is removed, the vascular system is again open. That is one of the concerns, and why you have to have a certain degree of pressure differential before you can start to get infiltration. It will vary from fruit to fruit. Some will have a stronger plug than others, and I gather in some cases the plug may not form totally. But once beyond that plug, as far as I can tell, the vascular system remains intact.

MS. OLIVER: Bob, were you done with your questions? Because you were next anyhow.

DR. BUCHANAN: Bob Buchanan, FDA.

[Laughter.]

DR. BUCHANAN: I just wanted to make sure our afternoon speakers didn't feel slighted, and so I do have a question for Bruce Tompkin.

Bruce, in your discussion of validation and validating processes, you didn't particularly focus on the role of microbiological testing in that process. Based on the Florida system, HACCP system or HACCP-like system, they require, in addition to the steps for surface-treating the fruit, they also require subsequent microbiological testing. Could you give us some comments on how such microbiological testing fits into a HACCP validation process and verification process?

DR. TOMPKIN: This is Bruce Tompkin.

I wrestled with that question throughout those slides. Actually, in--the intent of a HACCP system is to design the system such that you have confidence in the total system, the total food safety management system, so that you actually control the hazards. In those situations where you do not have a sufficient confidence level that the end product will be safe and meet your own criteria or regulatory criteria, then some end-product testing may be appropriate.

In my own case I know of two product systems where we did do end-product testing. We no longer have those systems in place, so I would view those situations as being of an interim nature till you have a better controlled system.

And so I think in terms of the orange juice system that we've been talking about, and these 5-log reductions, the goal is to reach a point whereby end-product testing--your confidence level is high enough that end-product testing is no longer needed or productive because the hazards of concern are below detection levels.

As for the data that we've been hearing with the E. coli, which is certainly very helpful information, and

useful as a process control--as a means to assess the level of control of the process, that's very helpful. The pathogen testing for Salmonella and E. coli 0157, that also is very helpful data, but the testing is not adequate for lot acceptance testing, and if we as a Committee wish to get into that, then we should consider a sampling plan, whether a sampling plan is appropriate, and John Kvenberg's already been talking in terms of 30 sub-samples being composited, for example. Whether you can do it in two 15 sublots, that's one approach. And then it's a question of the methodology. We have a lot of work to do in terms of even coming up with an acceptable end-product testing program.

Does that help?

MS. OLIVER: Did you have any other questions?

DR. BUCHANAN: No.

MS. OLIVER: Okay. Swami?

DR. SWAMINATHAN: Bala Swaminathan, CDC.

I have two comments on specific questions that were brought up yesterday, and then I have a request for the chair and a question.

First, responses to the two questions that were brought up. Dr. Donnelly asked about the CDC method. I do have a copy of the method now, and I'll be happy to share it with you, and if someone would make copies, others on the Committee.

As far as the regulated industry is concerned, my advice to you is to get the procedure from the FDA, not from us.

Secondly, Dr. Tompkin yesterday asked me if we had quantified the Salmonella from any of the outbreaks, and the answer is yes. We did quantify the numbers of Salmonella in the Florida outbreak, and it was 2 to 4 CFU per 100 ml.

Third, the request for the chair. I am easily confused, and I'm thoroughly still confused about the temperature differential, and I thought after Bob Buchanan's questions I had things under control and clarified, until Dr. Strobos pointed out that the oranges that are meant for fresh juice do not spend time in the cold room. It would be very useful for us, as we do our deliberations this afternoon, if one representative from California, perhaps, Dr. Arpaia, and one person from Florida, would draw a flow diagram starting from the tree, and give the ranges of temperatures that those oranges are exposed during the--until the juice is made, and if at any point the oranges come in contact with water, a cleaning solution or a disinfectant, provide the approximate temperature of that solution at that step. I think that would be extremely useful to me.

And finally a question for anyone who cares to answer this question. Is we have primarily focused on the top four questions that we were given, and we have not spent any time at all on the 5-log reduction related questions, and I would like some feedback from persons like Dr. Parish, Dr. Ismail and so forth, on whether in their opinion the 5-log reduction can be carried out in different steps at a different locations or how do they view this? Thank you.

MS. OLIVER: Okay. First I would ask both those that are here from Florida and California, if you would be able to draw a flow diagram, each of you, for the Committee for the afternoon?

DR. ARPAIA: Yes, I'm trying to get a

transparency.

MS. OLIVER: Fine, and we'll get one then for both Florida and California?

DR. STROBOS: Yes.

MS. OLIVER: Okay. We'll do that for this afternoon.

Then, Dr. Parish or anyone, can you answer the second question?

DR. PARISH: Regarding the cumulative 5-log, this is a philosophical issue that I've struggled with for years, and the Committee, this Committee did make that recommendation. I have had a great deal of difficulty understanding, when we first began, trying to comprehend what a 5-log reduction meant, especially with regards to the surface volume--surface area to volume issue. And I queried FDA folks, my colleagues there for a number of times. They got tired of me calling, actually, to try to understand exactly what that meant.

It was my understanding that if you consider one piece of fruit, and you assume--make an assumption or make a theoretical thought process, that there would be 105 organisms on that, pathogens on the surface of that one fruit, that when you juice that one fruit, in that juice there will be a 105 reduction of those organisms that might have been on the fruit as to what it gets in the juice.

When you stop and consider the volumes that are run and the volume of juice that's been produced, the empirical evidence seems to show that when you use good quality fruit that's produced properly, that's harvested properly, that's handled properly in a very well-cleaned and sanitized facility, and when the fruit itself is well cleaned and sanitized, that the empirical evidence seems to indicate that there--that the risk associated with that product is very low. Now, we don't have a specific number to put on that risk, and one thing I've tried to come to grips with is the fact that every bite of food that we take has a degree of risk associated with it, whether it be the orange juice I drank yesterday morning, or whether it would be the wrap I had for lunch yesterday at the counter. And the question comes in, what is acceptable risk? According to this Committee, 105 log reduction is an acceptable risk, and I've just accepted that as being what FDA thinks is appropriate.

MS. OLIVER: Did anyone else want to respond to that question? Dane?

DR. BERNARD: Thank you. Dane Bernard.

It's one of these issues that a good idea has many parents, and a bad one is an orphan. And I'm not sure where the 5-log falls at this point in time. However, having been at least associated with the deliberations, the thought--at least my impression at that time, was that in the absence of great amounts of data, an operation which

were being run under even fair GMPs should have produced a juice with a moderate amount of bugs in the juice and then a process applied to the juice. Conservatively, a 5-log process applied to the juice would reduce the contaminants that were there to a level where they would not result in a public health risk. That's my impression of the thinking that was there.

Now, since this issue has developed, I have to agree with Dr. Parish, it depends on who you talk to as to

what that number means, how it is to be applied, and when you begin looking at the fruit and decontaminating the fruit, and taking credit for a portion of the log reduction in decontaminating the fruit. I think that that thinking, while it--theoretically, there's nothing wrong with it, that probably goes beyond the original concept that we had discussed when we came up with it. Now, that doesn't mean it's wrong. It's just that the original thinking was to apply a treatment to where we come up with a level in the finished product that is not going to result in a public health risk. And when you start with, say, 107 or 109, obviously a 5-log reduction is not going to be enough if that were in the juice itself.

On the other hand, if you start out with very low numbers, applying a 5-log is a very conservative number. So it depends on how you want to look at it, but those were some of the considerations.

I'd also like to ask, since there is, I think, still opportunity for questions. We had a presentation by Laurie Girand, and one of the concerns she brought up was a concern that their group has over the adequacy of the 5-log and maybe Laurie would have something to add. Maybe they're not satisfied yet. There's been some discussion, but maybe we could get a revisit of the questions that STOP had regarding the 5-log.

MS. OLIVER: Laurie?

MS. GIRAND: Laurie Girand, STOP.

We distributed yesterday the background on that slide that was shown to you yesterday in paper, so I think you now have it in your binder. We had, I believe, 7 points that we thought called into question the validity of 5 in particular as the number. The first was that the--one of the at-risk groups consumes substantially more juice than the Committee assumed. The Committee's initial assumption was 100 milliliters per day, and we have statistics showing that some infants and small children drink as much as 10 times that amount, which seemed to be off by a log, so that was of concern.

The second point was that it wasn't clear to us that the number of pathogens in animal feces had been accurately assumed for both Salmonella and E. coli. We have information revealed at the November meeting by Jurs Strobos in particular, that we had a quote from him that said that the level of pathogenic organisms that you get in fecal contaminants is 1011 to 1012, and that was quite an order off from the 104, 105 that the Committee assumed based on the data that we have. We might be comparing Salmonella to E. coli, and that might be the difference there, but it was a pretty substantial difference.

We have gone over different grading issues that we don't believe the Committee considered in the past, which we believe contributes to the amount of contaminant or the potential for contaminant. We've also gone over temperature changes, which will be considered to be an issue. I think theoretically one of the questions, as long as you're still dealing with theory, is why do you see repeated Salmonella contamination in orange juice? If it was a plant problem and a processing problem--when I say "plant", excuse me-- a facility-related problem or a processing problem, why would you not see other types of contamination in orange juice? And we're not seeing outbreaks from other types, which

suggests that something from--and I don't know where--it could still be in the processing plant, but somewhere between the orange and the plant, something is selecting for Salmonella as opposed to other organisms.

We are very concerned that the Committee only really viewed fruit as coming in maybe 1 piece in 100 being contaminated. Clearly, one of the fundamental problems that we have, and epidemiologists have in tracing back these outbreaks, is that the fruit that went to the batch is gone by the time they get to the site, and in fact, sometimes even the orchards have been cleaned up by the time the investigators get to the site. And so when you might have, for example, as it appeared to be the case in the Odwalla outbreak, a single orchard shipping off a large batch of fruit which might have had a significant percentage of it picked up off the ground, you're not selecting necessarily for the circumstance. When you talk about 1 in 100, where an orchard might fertilize--we haven't heard a lot about chicken manure--but fertilizing with chicken manure, and in fact, multiple pieces of fruit, more than 1 in 100, would have been selected, and in fact, FDA studies show that even growers, apple growers in this case, claim that they use as much as 10 percent of dropped apples in juice, and that's again off by a log from where you originally started.

We have concerns about the contamination rate. It sounds like you have one piece of data which we didn't have yet, which is that you've seen 2.4 CFU per ml in the Disney World outbreak, but we don't seem to have data on the others, and I don't know where that's going to go. We are seeing isolated examples in multiple FDA related and outbreak-related data, and actually, Martha Roberts from Florida's data, where they get a case of more or 100 or more fecal organisms per ml they found in studies between, I think, 1996 and 1997, that 4 to 5 percent of samples in firms in Florida had some level of contamination.

And lastly, we're very concerned about this what we'll refer to as the pseudo-validation of this with eggs and salami. Salami is being increasingly recalled for E coli 0157:H7 contamination, which we believe--and this test number about E. coli contamination in meat suggests that a 5-log may not in fact be sufficient for salami, and the pasteurization of eggs, it's my understanding, was formed by the ARS. It wasn't necessarily scientifically validated. It was part of bake-offs and marketing that yielded the current 5-log for pasteurized eggs, which is what the company was comparing it to.

So along the lines, across those 7 points, there seem to be enough validation or enough data that suggested that maybe at least one of these points would undermine 5, and suggest that maybe 6 would have been safer.

Do you have any more questions? Dane, did I answer your question?

DR. BERNARD: Yes.

MS. GIRAND: Thank you.

MS. OLIVER: Jur, did you have a comment to that?

DR. STROBOS: Well, yes. She apparently quoted me, and I just wanted to--first of all, I'm not aware of where--

MS. OLIVER: Can you identify yourself, please?

DR. STROBOS: Yeah. My name is Jur Strobos. Just three very small comments.

One is: my assumption--and it's clearly an assumption--is that the differences between apples and oranges that we're talking about and the differences between Salmonella and E. coli have some reflection on the different flora and fauna that are present in the environments where apples are grown versus those where oranges are grown, especially in Florida where there are a fair number of amphibians, and I think at least in the theme park episode that was discussed earlier, you know, there was an issue of potential amphibian contamination that you talked about.

As another point of clarification, I believe your clarification was 2.4 CFU per 100 ml, not per ml, as she stated.

Finally, she quoted me as saying that I thought the contamination of Salmonella was 1011. That was a question, not a statement.

My question, and it's still a sort of, as far as I know of, open question is: if there is natural contamination from let's say amphibian feces on an orange surface, or some sort of animal contamination of that nature, I'm not aware of what the concentration of the Salmonella organisms endemic in amphibians that are present in the environment is. And my question was whether it is 104 or 1011. I don't think we really know the answer. If there's anyone on this Committee that knows the answer, I'd be very interested in that, but I certainly have no knowledge of what that endemic level of contaminant might or could be.

MS. OLIVER: John?

DR. KVENBERG: Thank you. John Kvenberg, Food and Drug Administration.

MS. OLIVER: Can you speak into the microphone, please?

DR. KVENBERG: John Kvenberg, Food and Drug Administration.

Back to the issue that Dr. Buchanan had brought up, and was previously discussed by Dr. Doyle. If I could have some help from Dr. Ismail on the Florida plan relative to the utilization of E. coli and what the rules are?

I have been struggling with the Tab D of our notebooks, trying to make a determination of what exactly the procedures are and the requirements are within the Florida program on finished product testing, what--I'm referring to the section called 3.27, which is Tab (d), small d, under the Citrus Products Inspectors Instructions. And I simply can't find out the specifics of how the E. coli testing is done. Does it depend on the size of volume that's put out? Who does the testing and what are the procedures? We don't appear to have that document that covers the E. coli in this 1996 program that the Department of Citrus has. And you can help me, Dr. Ismail, on what E. coli testing protocols and procedures are by the Florida Department of Citrus?

DR. ISMAIL: Where are you looking?

DR. KVENBERG: I'm looking--I may not be correct, but what we were provided was under Tab D in our notebook. It's called 3.27. It starts out, "Unpasteurized citrus juice inspectors instruction." And I'm looking at--every page appears to have a letter on it. It appears that the microbial section, which is 3.2.7(f) begins to talk about total plate count numbers.

Is there some procedure that we're missing in the document that speaks to the E. coli testing requirement? Who does it? Is it associated with volume and production? How frequently? I just don't see any information on the E. coli indicator testing procedures in what we have.

DR. ISMAIL: This is Mohamed Ismail, Florida Department of Citrus. I don't have the specific information on the type of testing, but MaryGrace Sexton, having a facility that is under USDA inspection and subjected to consistent testing in day-to-day operation of this, I would like to call on her to clarify this point.

MS. SEXTON: MaryGrace Sexton, Orchid Island Juice Company.

The procedure is that every single day we run, every single day we have a USDA inspector on site, and every batch is then tested at an outside lab. If I recall correctly, it is mandated in those rules that an outside independent lab test these. This all came down when they had their--it got very strict when it came--the situation in Florida, the theme park, and at that time Dr. Parish helped us interpret the tests that they wanted to use.

Is that true, Dr. Parish?

MS. OLIVER: Dr. Parish, can you interpret?

DR. PARISH: Mickey Parish, University of Florida.

The regulation, John, to my knowledge, does not specify a test method specifically. It simply says that the processors shall conduct tests on total counts--help me out here--coliforms, E. coli, in an effort to try to establish that the process is somehow under control.

DR. KVENBERG: Let me read to you the specific that I've seen, and maybe you can help me interpret it. It's under Section E of the instructions to what you do, and I assume it's the Florida Department of Citrus through the contract arrangement with USDA inspection.

Section E, subset 2. "The processor shall have a microbiological program and the inspector shall verify that the program includes results from total plate counts and an absence of fecal coliform and E. coli for whatever production lot of each day"--let me read it slowly--"for each production lot or each day's production, whichever is less."

So how is that done? Is that a simple grab sample from--that is, the processor shall have this done? Maybe MaryGrace Sexton can help me. How do you do it?

DR. PARISH: I could not address that. I think the processors individually do that different ways.

DR. KVENBERG: Maybe you could help me.

MS. SEXTON: And I don't mean to come across as being ignorant, because I'm not, but the question is, is at some point when they were getting very sophisticated in the orange juice testing, this serum was of very much interest to get the most accurate test. Now, as it has developed and evolved, I believe the CDC has even had their input in the protocol of the testing, and every time there's a governmental agency that shows a concern of any sort, then there is--it popped up immediately that we then transfer our testing to what you want. So I don't want you to think I'm ignorant, but there are serums that--you know, there's the orange serum that sometimes you want. Then you do a little bit more study and you bring a different kind of serum. And we respond to whatever you want.

When the CDC responded this last time, we immediately called the lab to verify that they were using the exact protocol the CDC was doing.

DR. KVENBERG: Well, let me try again because this is a very specific question. I think you can get--

MS. SEXTON: About when we pull the tests?

DR. KVENBERG: No. How do you do it?

MS. SEXTON: Pull the test?

DR. KVENBERG: It's done every day--is it done every day, and are you required, or do you--

MS. SEXTON: It's taken right off the bottling line. There are 8-ounce samples, and they are put in a cooler, and they are overnight-expressed or personally transported to the outside lab.

DR. KVENBERG: Thank you.

MS. OLIVER: Any follow up?

DR. STROBOS: Let me just--for the record. I think we--John actually answered that question, and Dr. Parish, earlier this afternoon, gave sort of a detailed description of exactly when the sampling was taken, the batches and so forth, in response to Peggy Neill's question.

Let me reiterate that we are advocating as a Florida model, what we're asking for is a national system that builds on that system. It doesn't necessarily have to be identical in every piece. What we would like to do is build on that experience and create a national system. So, again, we are looking for your recommendations in terms of what the appropriate system is, building on that experience.

MS. OLIVER: What I would like to do is try to keep our comments related to the questions from the Committee and focus on the answers that we need.

Bob, you have a follow-up quickly to that?

DR. BUCHANAN: Yes, I just want a clarification. This is Bob Buchanan from FDA. Also outlined in that document is a sampling plan based on the number of samples that have to be taken in correlation with the amount of juice that's produced.

DR. KVENBERG: Under section K?

DR. BUCHANAN: Under section K. Is that sampling plan followed? And it's not clear on the size of the sample.

DR. KVENBERG: Madam Chair, if I could, that was basically my question, too. My confusion goes to exactly that point.

MS. OLIVER: Would you identify yourself?

DR. KVENBERG: John Kvenberg, Food and Drug Administration. Yes, section K basically--I'm not clear in how this is written, but it doesn't appear that sample size under this section applies. It looks like a one-ounce sample per day going back to the other section is all they do. That's what it looks like.

MS. OLIVER: Okay. Bob, were you looking for a response?

DR. BUCHANAN: Yes. I'd sort of like to find out if in practice the sampling plan as laid out in this document is actually followed or if it's just a single sample that's taken each day, regardless of the production of the plant.

MS. OLIVER: Might I might ask does anyone have that answer from any of the plants that are here if you take a sample according to the plan there or if it's a single

sample each day?

MS. SEXTON: I'm MaryGrace Sexton, Orchid Island Juice Company. Are you asking is there a sample taken from every batch that is processed?

DR. BUCHANAN: In this document, on page 3.2.7K, there is a chart that says retail fresh juice, all types of products, containers, sizes, and counts. Then there's a table that indicates number of gallons produced--I assume per day. It ranges from 1,500 or less up to 4,200 to 7,200--72,000, I'm sorry.

At each of these there are six--five categories. There's a different number of samples that are required. At the lowest category, three samples are require. At the next it's 6, 13, 21, 29. And I just--is there--is this being used by--

MS. SEXTON: Okay. I would say yes, because what--are you--are they stating that--is that a production day or tank fill? So I'm going to go read that document.

DR. BUCHANAN: Okay.

MS. SEXTON: Okay? Because I would say, yes, it is being followed.

DR. BUCHANAN: How many gallons do you produce a day and how many samples do you take a day? That's, I guess, the way I want to ask it.

MS. OLIVER: I think if you would just--we could give you the document to go look at and read, and then if you could even call back to find out if you need to, that would be--

MS. SEXTON: No, I'll address that.

MS. OLIVER: Okay. That would be fine. We'll give you--we'll go through other questions and come back to that. Just let us know when you're ready. Okay?

Jim Anders?

DR. ANDERS: Yes, Jim Anders, North Dakota Health Department.

My first comment is about the 5-log reduction. I have a problem with that because that was designed--and I think Dane kind of hit on that. It was designed in products in which there was heavy contamination to begin with.

My question yesterday was--

DR. BUCHANAN: No.

DR. ANDERS: Well, there was a connection between general organisms and pathogenic organisms. There was not?

DR. BUCHANAN: No.

DR. ANDERS: Well, then, there's some question in my validity--a question of the validity of a 5-log reduction to start with. But basically yesterday I had asked whether there was any studies to show that there were any pathogenic organisms on these--I guess I asked it this morning, and it was finally answered, that no studies had really shown that there were any organisms here.

But let's assume that there were organisms here. Then my question of industry is--because after--some of them said that they actually did testing that was sent out and--but the common practice in food processing is to, even if they're going to test the product, that they release the product to supermarkets and that type of thing. That's why we end up with recalls because even when they then test their product and they find that something is wrong with it, they've already released it, and then they bring it back. And in the process, sometimes the public has actually

consumed some of those products.

So my question here is of the industry, since we don't have rapid tests, we don't have tests that are--they're working on those, by the way, but since there are not tests that are due in four hours or so, for those that are bottling--now, I realize, keeping in mind here now that if they're producing it today, there's no way they can test it today, if they're producing it and they're going to drink it today. But if they're putting it in bottles and then they are--or packages and they're shipping it out, with the testing that's being done--and some of them said they were doing testing on this--are they releasing the product before they get the results of these tests? Or are they doing this and then having to recall it if it's got a positive?

DR. BUCHANAN: Janice, can I answer the first part of that question?

MS. OLIVER: Yes, go ahead.

DR. BUCHANAN: I was chair of the working group, produce working group--Bob Buchanan, FDA--at the time that these deliberations took place. The process that was used after hearing public comment and examining as much of the scientific information as we had available, the process that was used was in agreement and in accordance with the process outlined by Bruce Tompkin. That was there was a consideration of what was the best data we had on initial levels. There was a consideration of the number of log cycles it needed to be in terms of your target level of protection that was being sought. There was an evaluation of whether or not the organisms could grow in juice. And in this case, it was assumed that they could not grow in juice.

So that we specifically went through each of those four phases of the equation that Bruce put up on his overhead or his slide. While I can't say that that process was reduced to a formula such as he had placed it, each one of those specific items were addressed and evaluated using the best available scientific information that the Committee had at that time. And this was, as you--when we solve that equation, this is what was felt was the appropriate level of protection based on the information we had on the incidence and levels of pathogens present on both incoming fruit and in the juice.

DR. ISMAIL: Mohamed Ismail, Florida Department of Citrus. In response to Dr. Anders, there is a paper by Steven Pao and Eldon Brown in which a statement is made that no E. coli was recovered from fruit at the end of packinghouse processing and no Salmonella were found on fruit during the entire processing. You have that paper in your packet. We provided that, so I would like to say that there has been some work done on detection of organisms such as E. coli and Salmonella on fresh fruit going through the packinghouse, and it was done in a survey of seven commercial citrus packinghouses.

As far as the specifications on the fresh fruit that goes into processing, whether it is fresh or--fresh non-pasteurized or pasteurized, processed, the specifications throughout the Florida citrus code and the Florida Department of Citrus rules have a description of the fruit that must be processed or packed, and it emphasizes the absence of defects, and wholesomeness. Whether it is processed by heat treatment or going into fresh, it has to be wholesome, it has to be sound, and any fruit that is not

sound must be discarded.

So there is a specification. I did say something this morning or maybe yesterday that we don't have any specifications for fruit going into fresh juice, but the fresh juice, including processing and non-pasteurized or pasteurized, fruit has to be wholesome and absent--have absence of any defects.

DR. ANDERS: Well, thank you. Just one quick comment, and that is, a 5-log reduction of nothing is nothing. That's my comment here.

But, anyway, yes, I'm still asking for the industry's response to release of a product that has perhaps not had the results in.

DR. ISMAIL: In general, we find approximately between 104 and 105 log of colony-forming units of microorganisms on the surface of the fruit that is harvested from Florida citrus groves. That's the range we find. We do not find 109. We don't find 108. We actually have to do a great deal of our work to test chemicals or heat treatment, has to be inoculated to bring the level up to where we can test the efficacy of the treatment.

MS. OLIVER: Catherine?

DR. STROBOS: I believe he wanted an answer about industry practices with regard to the positives.

MS. OLIVER: Identify yourself and just--

DR. STROBOS: Yes, my name is Dr. Strobos. The question--remember that the--or recall that the fresh product has a 17-day shelf life. Obviously there are some, you know, transportation and storage issues before it gets to consumers. As we've shown, there haven't been any positives for pathogenic E. coli or for Salmonella, so there have been no recalls based upon that.

My understanding is that the few episodes where generic E. coli have been identified, that based on the test methodology becoming available or the test results becoming available relatively promptly, the test methods that were used, that those particular batches--and we're talking out of 17,000 batches. We're talking batches numbering on someone's--you know, the fingers of one's hand amongst these four companies, or something on that order, that those batches have not reached consumers and, therefore, have not technically been recalled. In other words, they've been--where they have been not released to distributors and, therefore, not entered the stream of commerce.

Now, that, of course, depends a lot on the test methodology that is being used. Were one to adopt a test methodology for which one would not have results for 72 or 48 hours, then the ability to institute that with a product that has a 17-day shelf life would be difficult.

DR. ANDERS: So am I to understand what you're saying is--you did mention this morning, now that--in some of those studies that there were some positives, but those never reached the market--

DR. STROBOS: That is my understanding.

DR. ANDERS: --by the time that you had the results of those, as far as you know.

DR. STROBOS: Yes. Based on the test methodologies being used at the time that those tests were obtained.

DR. ANDERS: But theoretically now it could reach the market. I mean, you are not holding that product--

DR. STROBOS: Theoretically--

DR. ANDERS: --before it's released.

DR. STROBOS: Theoretically--and, again, we are open to suggestions from the Committee about this. But under the circumstances that are currently taking place in these plants, the data is being made available in a way in which timely action can be taking place.

I want to reiterate, you know, Dr. Tompkin's comments that we're talking about multiple levels of control, and the microbial testing is intended not as a release criteria--I mean, that's not why it was adopted. It was adopted as a method of evaluating the process and the plant and for taking corrective actions.

So, you know, given the fact that there have been no Salmonella or pathogenic E. coli identified, there's been no corrective actions based on that.

When generic E. coli have been identified, the products have not reached the market, and there have been, you know, actions taken to review the processes and try and prove the process that may have resulted in that contamination.

DR. ANDERS: Thank you.

MS. OLIVER: Catherine?

DR. DONNELLY: I had some questions regarding--

MS. OLIVER: Please identify yourself for the record.

DR. DONNELLY: Oh, I'm sorry. Cathy Donnelly, University of Vermont.

I had some questions regarding the model HACCP program or the voluntary program in which some of the processors here are participating, and the first question is: Who has regulatory oversight in that program?

MS. OLIVER: What model HACCP program?

DR. DONNELLY: Isn't Orchid Island and--weren't there four companies that were participating in a--

MS. SEXTON: We're the FDA pilot program for the United States.

DR. DONNELLY: That's my question. So the FDA presumably has some regulatory jurisdiction over this pilot program. Is that correct?

MS. OLIVER: FDA has regulatory, you know, jurisdiction over fresh juice manufacturers that we're talking about and fresh citrus juice manufacturers.

DR. DONNELLY: Great. So then with that, if FDA were engaged in a pilot program, presumably there were a set of criteria that FDA was recommending--or maybe--I'm trying to get at this. It seems like during our deliberations this morning there are many more questions than there are answers. And at least the way I operate, I'm assuming if you run a pilot program, there were a set of criteria that the regulatory agency would be testing whether these criteria could be met. But based on our conversations this morning, simple things like verification procedures for testing--I don't care whether we're pasteurizing or not pasteurizing. In the absence of those methods, how can you verify? And I'm just wondering if someone could comment on the goals and objectives of the FDA pilot program with these manufacturers.

MS. OLIVER: John?

DR. KVENBERG: Thank you. John Kvenberg, Food and Drug Administration. Well, I'll try.

Basically the--well, there are two points just to avoid confusion. Under tab E of the document you got, the model HACCP plan for small-scale fresh squeezed non-pasteurized citrus orange products is a Florida document. It is not ours. So the material you have is--this is Florida Department of Citrus documentation.

Our pilot program basically is a study program that goes through the procedures of how a firm will execute the HACCP-based program. And, you know, I can speak with our relationship to Orchid Island and its validation studies. We reviewed the process that they had externally done, and it's been explained here, I believe yesterday, that they used actual pathogen testing on a simulated system, and we've reviewed that data on how they validated their system.

Do you have specific questions of our comments on that?

DR. DONNELLY: Well, I guess so many of the questions here are relating to methods and sampling and plans and all the specifics of presumably implementing a pilot program, and I'm just wondering if there's a written document that the FDA could share with this Committee regarding what your instructions to these manufacturers were for participation in this pilot program. Or was the goal more to learn answers to the many questions that we're all asking?

MS. OLIVER: Janice Oliver from FDA. One of the things I'd like to say is the FDA pilot program was a pilot program across the industry, across many types of industries. It was not a pilot program for just juice. It was not a program--and, John, you can add to this. It was not a program specifically giving methods of sampling, et cetera. It was a pilot program to see if HACCP would work in the industry, what controls had to be in place, the amount of paperwork, how it could be implemented. And we did not have specific instructions that were handed out doing it.

Each firm entered into agreement and a confidentiality agreement with FDA. FDA went out and did inspections of the facilities, on-site audits at that time.

John, did you want to supplement that?

DR. KVENBERG: Yes, John Kvenberg, Food and Drug Administration. That's absolutely correct. We sign a confidentiality agreement. However--and we seem to be running her legs off this morning. MaryGrace Sexton, who is out researching the other issue, has volunteered--you're back. Okay. She has her other answer, but is basically willing to share, I think, their validation information. She can speak to it better than I can.

We have reviewed this data. This is their data that we have reviewed and critiqued, and she can provide the information, I guess, on validation, if that's your concern.

DR. DONNELLY: Well, I guess more maybe to put you on the spot, John, after dealing with this pilot program, how do you feel the abilities for these fresh juice manufacturers to implement a HACCP program and its efficacy, where are we at there?

DR. KVENBERG: Well, the only experience, as I said in my opening remarks, with juice products within HACCP programs involved three firms. This was, as you may recall, Ocean Spray, which can be typified as a very large firm,

that has a corporate structure to it, and two small firms: Fresh Samantha was involved in out pilot, can be typified as a small firm in my eyes, as well as Orchid Island.

I guess we're here today talking about Orchid Island's ability to do a hazard analysis, come up with a HACCP plan, have it go through the seven steps, and conduct it. They've done that. And they're typified as a small firm that can go through that process.

MS. OLIVER: I think if you look at the--Janice Oliver, FDA. If you look at the questions--yes, I remembered myself.

[Laughter.]

MS. OLIVER: If you look at the questions we've asked the Committee, one of the things, I think, in the basis of doing the 5 log and in the pilot was based that 5 log and where do you start is the question we're having now, and that wasn't answered definitively before we had comments dealing with that.

Another thing is we have additional research that we have done in the meanwhile that has a question or a possibility of internalization of the pathogens that we're bringing to the Committee, too.

Another thing is that this pilot is ongoing and active. We have put out reports, and I think we do have them here, if you have comments, if you wanted to see the type of reports that we put out in evaluating HACCP and doing that, and we can give it to you when we break so you can look at that and see if that clarifies the questions that you have or if you have any additional questions of clarification from that. But the juice one is still ongoing.

MS. SEXTON: Can I clarify something?

MS. OLIVER: Sure.

MS. SEXTON: It was my understanding that when our Congressman got the meeting with Dr. Vanderveen, we went in and they were going to regulate fresh squeezed orange juice, and that time we asked them, Do you have a pilot program, or how are you going to regulate this? They said, oh, yes, we have one, meat and cheese. I said, sir, this is fresh squeezed orange juice.

At that time I thought a specific program was set up as a pilot program for the FDA for fresh squeezed orange juice. I--excuse me--am the pilot plan and I was under no understanding that it was in connection with other products. I thought we were supposed to be specifically studying fresh squeezed orange juice. That's what Dr. Vanderveen had told us.

The second clarification I have is this document that you keep responding to, I don't believe--I'm going to investigate it as I leave. I don't believe this is the Department of Citrus document that went--that everybody's referring to. I believe this is the Department of Agriculture document. So I think that's where people are getting confused.

DR. KVENBERG: Well, if I could, relative to our understanding, yes--

MS. OLIVER: John Kvenberg.

DR. KVENBERG: John Kvenberg, Food and Drug Administration. Your participation in our pilot program was specifically for studying HACCP applications in fresh squeezed orange juice. You're absolutely correct.

MS. SEXTON: Okay. That's what I was to understand.

MS. OLIVER: This is Janice Oliver, FDA, again. My comment was made that our HACCP pilot program was not just for fresh juice, that we had other companies in HACCP pilots that were not fresh juice. It was just part of a larger program.

MS. SEXTON: You're just talking about your department.

MS. OLIVER: Yes.

DR. BUCHANAN: Possibly you can help--

MS. OLIVER: Who are you?

DR. BUCHANAN: Bob Buchanan, FDA.

[Laughter.]

DR. BUCHANAN: You can help clear up, I guess, some of the confusion that's around the table. My understanding when you say USDA inspection, you are not referring to the regulatory agency FSIS, but you're referring to the marketing agency AMS.

MS. SEXTON: Now, that is something you're going to have to deal with because that's what you define it as. But as of two and a half years ago, they could shut us down for safety issues. They can come down and shut us down for any issue that is a safety issue to a consumer. They have taken that authority upon themselves, and we have documentation that they require reports that are not marketing reports. And I know that you want to make light of that, but it's very important that I reiterate this, because when it gets in your field, you want to say it's a marketing arm, and I am telling you they come in and severely inspect us.

DR. BUCHANAN: Let me further--

MS. SEXTON: And not just for quality.

DR. BUCHANAN: --ask that question. This is a fee-for-service. You pay to have these inspectors there.

MS. SEXTON: Right.

DR. BUCHANAN: So you've entered into a contractual arrangement with them in terms of this inspection. This is not a regulatory inspection.

MS. SEXTON: It is mandatory in the State of Florida.

DR. BUCHANAN: It's not mandatory at the federal level.

MS. OLIVER: Okay. I think there's some confusion and some question about that. We'll try to get some clarification if we can at all at lunchtime and we'll see if it's of necessity to the Committee, and I'll ask that.

MS. SEXTON: And then the third thing that you asked about is the 5 log, can it be done. We have the documentation from ABC Research that I hope everyone knows. It's a well-renowned lab that has the validation of the 6.7 log.

MS. OLIVER: Okay. We'll have that available for the Committee.

Bruce, you had some questions?

DR. TOMPKIN: Yes, I do. This is Bruce Tompkin.

We had some information then provided--Swami, I really appreciate it--on the number of Salmonella in the Florida outbreak. We're talking then about 2 to 4 cells--and that's just one, probably a few analyses, or maybe even only one--per 100 ml. And I was interested in knowing

whether any information was available on the Sun Orchard outbreak in terms of numbers of Salmonella.

MS. OLIVER: Dane?

DR. BERNARD: Thanks. Dane Bernard. Let's take John's intervention first.

DR. KOBAYASHI: On this testing that we did--

MS. OLIVER: Can you identify yourself?

DR. KOBAYASHI: Sorry. John Kobayashi, Washington State Health Department.

On the investigation that we did on the implicated juice, there was one sample that was positive. Our laboratory quantitation showed that there were 68 Salmonella per cc. This was serial dilution, so it's possible to have an order of magnitude difference on either side. Estimating from an eight-ounce glass, that would extrapolate to about 15,000 organisms per serving.

The other general point of interest might be that we studied several cohorts of individuals who all drank the orange juice, and within those cohorts there was a 50 percent attack rate on diarrhea. Extrapolating from the amount of juice served in Washington State during the outbreak period, we estimate that there were perhaps 10,000 individuals who became ill related to the outbreak, or a ratio of 100 to 1 with regards to positive individuals for Salmonella. For every case of Salmonella reported to us during the outbreak period there could have been 100 individuals ill with salmonellosis related to the outbreak.

MS. OLIVER: Bruce, did you have a follow-up question?

DR. TOMPKIN: No, I think that's it. Thank you very much.

MS. OLIVER: Dane?

DR. BERNARD: Thank you. Dane Bernard.

Further to the 5-log issue, I think Bob has restated that our intent was pathogenic organisms in juice, not total count or anything like that. We were looking at potential for pathogens.

Among the many unique things about the proposed rule on juice HACCP, there is a second criteria, which is stated no less than 4 times, possibly more than that, in the preamble to that rule, which basically lays out the level of protection that the 5 log is intended to achieve. That is the real target. Most people don't know how to deal with that, so the focus has been on the 5 log and where to start counting 5 log. But within the preamble to the rule--and I don't want to misstate it so I'm not going to read it here, but if you're going to look it up, it talks about the probability of illness per year based on a certain level of consumption of the same juice. That is the real criteria.

So when you talk about the 5 log and how to apply it and how to interpret it, if I look at that criterion and I look at some of the interpretations of a 5-log reduction, I'm really not too impressed with somebody that starts with a 7 log on the outside of a fruit, gets it down to 2 log, and says they've accomplished the intent of the rule. That was not the intent of the criterion that this Committee recommended.

MS. OLIVER: We have two, then I'll take these last two questions before we break for lunch.

DR. LIANG: Art Liang, CDC. I don't know if this is a meaningful question, but could someone compare and

contrast Sun Orchard's operations to the industry best practices or to the operations of the consortium.

MS. OLIVER: No, I don't think that--

DR. LIANG: Can't do that?

MS. OLIVER: No.

DR. LIANG: Okay. I'll withdraw.

MS. OLIVER: Are there any more questions? Dane, do you have another--

DR. BERNARD: No.

MS. OLIVER: Are there any more questions that the Committee thinks they need answered before this afternoon?

[No response.]

MS. OLIVER: Okay. What we have this afternoon is--

MS. SEXTON: Did you think we didn't have an answer--did you think nobody could answer that or did you just not want an answer?

MS. OLIVER: No, I just didn't think--

MS. SEXTON: You don't want an answer.

MS. OLIVER: Right. I just don't think it's appropriate to the deliberations of the Committee and the questions that we're asking.

What I'd like to do is take an hour and 15 minutes, come back at 1:30. That would give industry a chance to look and put together the flow diagrams in Florida and California to start off with this afternoon. Then there could be a couple questions of clarification, and then the Committee will have discussion amongst yourselves for about an hour.

[Whereupon, at 12:15 p.m., a luncheon recess was taken to reconvene at 1:30 p.m., this same day.]

AFTERNOON SESSION

[1:32 p.m.]

MS. OLIVER: We need to start back because we have a number of people who are going to have early planes this afternoon, and I want to make sure that I get the input from the group. I've gotten input from Larry Beuchat that I want to read after 2:00, but we had asked the industry to present flow diagrams from Florida and California. Are those people who are going to present the flow diagrams here?

[No response.]

MS. OLIVER: Might I ask a question of the times the Committee members have to leave, might I just ask a question of who has to leave before 3:00? Because I will make sure that when I am polling the Committee I will poll those individuals first.

[No response.]

MS. OLIVER: No one has answered for sure. Okay. Alison?

DR. O'BRIEN: I leave at 3:00.

MS. OLIVER: You leave at 3:00. Okay, fine. And, Nancy, you may leave early?

MS. NAGLE: Yes.

MS. OLIVER: Okay.

MS. NAGLE: Janice, what time do you think we'll get done?

MS. OLIVER: We probably will end up getting done closer to 4:00.

What I'm going to do, I'll tell you the process

I'm going to go through, and I'll ask a question now. I was going to have the flow diagrams done and give each five minutes to do it so we could move on from there. And then I was going to after that read Larry Beuchat's statement to the Committee and ask if you wanted any discussion before we ended up and I went around the Committee, and I was going to poll the Committee individually. And how I was going to ask the Committee to give me their responses was in two groups: ask the Committee to--that we've presented you with a number of questions in two areas: internalization and survival of pathogens, and the application and measurement of the 5-log reduction standard. I was going to ask the Committee to respond individually on internalization and survival of pathogens, if you could respond to those and just go around and have you respond as individually in the whole group as opposed to asking you each and every question, because I think that would take a long period of time, and then go and do the application and measurement of 5-log reduction.

A question I had was whether the Committee needed or wanted any time for discussion before doing that, and you know better than I. So while we're waiting for those individuals to come in on the other, what I might ask is: Does the Committee want discussion?

DR. SPERBER: Madam Chair?

MS. OLIVER: Yes?

DR. SPERBER: Bill Sperber, Cargill. I know I'm talking less than my colleagues. We have a lot of points we want to discuss. But I think that a lot of the discussion will fall out from the questions that have been asked, and it might just be more productive to go through the questions first.

MS. OLIVER: Okay.

DR. SPERBER: Then we could come to agreement on some broader discussion topics.

MS. OLIVER: Okay, fine. In the interest of time, should I read Dr. Beuchat's statements that he has here and read them into the record so you all have them, he left his comment? Okay. Let me do this. This is the comments from Larry Beuchat. It says, "To NACMCF: The following are some conclusions and comments offered for the Committee's consideration in the course of discussions leading to recommendations on pasteurization of citrus"--he says "on pasteurization of citrus juice."

"Evidence exists to support the likelihood of infiltration of microorganisms, including pathogenic bacteria in tissues and/or on areas of the skin surface that protect against contact with sanitizers, and, therefore, removal or inactivation prior to juicing.

"Two, the efficacy of sanitizers for killing pathogenic bacteria and other microorganisms lodged in protected areas on the citrus fruit surface has not been established through appropriately designed experiments.

"Three, information on survival of pathogens on the surface or internalized in tissues of citrus fruits as affected by temperature, relative humidity, atmospheric pressure, and other environmental factors, particularly if these conditions fluctuate over time, is lacking.

"Four, evidence for preventing cross-contamination of juice with microorganisms on the surface and/or internalized in the skin, albedo, or other tissues of citrus fruits during the squeezing process, either using

specialized FMC or other equipment, has not been documented.

"Five, survival of pathogenic bacteria in orange juice stored at refrigeration temperature for a period of time not exceeding its shelf life has been documented in laboratory experiments and in a commercially processed product.

"Thank you for the opportunity to contribute to the Committee's activity." And it's signed Larry Beuchat.

Okay. Might I ask if the individuals who are going to present the flow diagrams are here yet?

DR. STROBOS: Yes.

MS. OLIVER: Okay. If you could present the flow charts, I'd like to give about five minutes for Florida and five minutes for California.

DR. ISMAIL: I will introduce myself again. Mohamed Ismail, Florida Department of Citrus. This is definitely a highly estimated, approximate figures on the temperature change. I assume this is what was the question. Perhaps somebody can articulate the question.

MS. OLIVER: I thought there was going to be a flow chart. You might be answering a different question. There was going to be a flow diagram presented from the State of Florida and from the State of California on the processing of citrus juice, fresh citrus juice, taking it through the temperatures and how it's processed.

DR. ISMAIL: I did not prepare a flow chart. I did prepare a table, which can serve the same purpose, I'm sure.

MS. OLIVER: Okay.

DR. ISMAIL: This is an estimate--

MS. JACKSON: Can you speak into the microphone, please?

DR. ISMAIL: At harvest time, in the wintertime, you may encounter temperatures as low as 45 degrees and perhaps 70 degrees, and that would be during the month of November, December, January. And in the fall and the spring, the temperature of the fruit at harvest time could be at 80 to 90--I am not even sure of the 90 because it could be that the effect of transpiration on the tree can moderate the temperature in the atmosphere versus the temperature of the fruit surface itself.

Municipal water, depending on the time of year, could be between 70 and 75 degrees in Florida. That would be the water that one would use in a packinghouse situation. If there are some heating--I don't think we have any soak tanks that would require any heating of the water.

Fruit in the fall is de-greened at 85 degrees Fahrenheit. De-greening is like what they do with banana. They put the fruit, which is green, at 85 degrees with five parts per million ethylene to stimulate chlorophyll breakdown and enhance the development of color. And the fruit leaving the de-greening room could be at 85 degrees, 85 to 90 degrees, maybe.

After washing, sanitizing, and packing in the packinghouse, during the fall I estimate that it would be about 85 degrees, and the falls months would be October and--September and October, and the winter, maybe about 65, and during the summer, about 85 degrees.

There are also--this is going through packinghouses. If the fruit goes from the grove directly to the juice operation, then it would fall within these ranges

here, 45 to 70 degrees, and as we mentioned, there is hardly any soak tanks. There may be one or two in the State of Florida, but it is not a common practice. In juice operations, no one uses a soak tank, and at some point we had some packinghouses that had soak tanks that would be used for treatment against citrus canker, which is a plant pathogen. And these tanks would require a residence time of about two minutes. And it is either in 200 parts per million chlorine or in about 200 parts per million of sodium orthophenylphenate, which is an antibacterial, antifungal agent or chemical.

Storage is--we definitely recommend storage as required by the U.S. Department of Agriculture, about 33 degrees, and grapefruit, we don't recommend 33, but some industry people, they tell me that it is about 33, the same. But chilling injury is one of the disadvantages of grapefruit. Grapefruit is more of a tropical fruit, and it is very susceptible to chilling injury. Therefore, storage temperature, now we recommend 45 or even above, but above that we have a different disorder that can affect grapefruit. So we settled on 45 degrees.

The harvest for juice operations, even the ones that keep fruit during summertime for storage, they don't go beyond May, and at that time there is--this is not the rainy season in Florida, so they usually go through May. Harvesting for processing plants can continue into May, June, and even part of July. And let's say this is a very, very uneducated estimate, and I think it does reflect the struggle that you and us are going through, that we don't have enough information, even some basic things. And if I have it, I don't have it here.

We didn't exactly know what we are coming here for, other than to look into the issue of infiltration and to look at the experiments that the Food and Drug Administration designed and conducted in the lab under extreme conditions. So just speculating that it could be--between the beginning of a thunderstorm and the end of a thunderstorm, it could be about a 10- to 15-degree drop in air temperature. That doesn't necessarily mean that the fruit itself goes down by 10 to 15 degrees.

And, again, I would like to indicate that cold stored fruit are--whenever it comes out of storage, are re-washed. They are put again on the line. They are put through a packing line where they are re-washed, sanitized, graded prior to juicing. So it goes through an exhaustive surface cleaning.

Then in the packinghouse, the same thing. We can attest to the safety of our fresh fruit. It is washed, sanitized, graded, waxed, dried, and so on, before packing.

That's it.

MS. OLIVER: Thank you very much.

Dr. Arpaia?

DR. ARPAIA: I'm going to have to write on the overhead as I go because I only just--I had trouble getting the information.

MS. OLIVER: Does that mike come on?

DR. ARPAIA: I didn't want to get up and give my best estimates, so I contacted Bob Elliott, who works for Sunkist, who works in the packinghouses in California so that I could get a more accurate estimate of orange house conditions and fruit conditions.

In California, the fruit that go through a commercial packinghouse, we have navel and Valencia oranges. They're picked at very distinctive times of the year, and we also have different growing regions where the temperatures are slightly different between the growing regions, and so I wanted to talk to Bob about this. So I'll cover navel oranges first because I've actually completed the table for that.

San Joaquin Valley, Sacramento Valley accounts for approximately about 90 percent of all the navel oranges in California. The harvest season is between mid-October and May. The average ambient temperature at the time that we pick fruit--we don't pick the fruit when it's very, very cold because normally it's very damp when it's very cold, and we don't like to pick wet fruit. We estimated that the average ambient temperature would be between 45 and 75 degrees Fahrenheit because we're talking about mid-October to May.

The pulp temperature of the fruit coming into the packinghouse would be very close to what the ambient conditions are, so, again, 45 to 75 degrees Fahrenheit.

Normally, however, we don't like to run cold fruit over the line, as I indicated yesterday, and if the fruit are very cold, typically the fruit will be brought into the packinghouse and held overnight in a staging area. So the fruit does sort of moderate the temperature, and the estimate that Bob had based on some experience in doing pulp temperatures is that in these winter months in the San Joaquin Valley, the pulp temperature when the fruit is actually dumped onto the line would be between 55 and 70 degrees Fahrenheit.

If the fruit have been de-greened, early-season navels already green, then pulp temperature would be very close to 70 degrees because we de-green at between 68 and 72 degrees Fahrenheit. The packinghouse average temperature would be between 55 and 70 degrees Fahrenheit.

Cold room temperatures, Sunkist is recommending 37 degrees. He says some houses run as high as 45, but the average would be between 37 and 41 degrees. The fruit are typically in the hold room zero to three days with the pulp temperature coming out of these rooms--because there's no forced-air cooling going on, this is all passive cooling--would be around 41 to 45 degrees if it stays in at the longer period of time.

Water temperature, again, we only have two to three rinses on the line. The duration of the fruit under these rinses is under two seconds. And then if they have a tank treatment, the tank treatments typically average one and a half to two minutes. So we're not talking long durations in the tank.

Mr. Elliott indicated to me that he has done some testing of the change in fruit temperature in the tank, and if the fruit was 55 degrees Fahrenheit, he said the core of the fruit only warmed up one to two degrees Fahrenheit, and the actual surface of the fruit was somewhat higher but did not warm substantially, even in a heated tank of 105 degrees.

But, anyway, ambient water temperature would be 50 to 55 degrees, again, less than two seconds under these sprays. Tank, one and a half to two minutes. If the tank is heated, it would be 90 to 105; otherwise, for the sodium

bicarbonate tank we like to see around seventy--I didn't write that down, but it would be 65 to 70 degrees.

Some houses have a heated rinse after the high-pressure washer, again, less than two seconds under this, but it would be about 120 degrees to heat that water to. But, again, the exposure is under two seconds.

If you move to the inland empire--this is a small percentage of our industry--the harvest season is December through March, and you can see they're slightly warmer temperatures. But if you go down through here, the temperatures are going to be about the same.

Now, if we move to Valencia oranges, which account for about 25 percent of all the oranges grown in California, we have a different harvesting season. Here the fruit are being harvested in the spring and the summer months versus the winter and spring months. So in the San Joaquin Valley, harvest is between mid-April and October. The ambient temperatures here would be 55 to 90 degrees Fahrenheit. Pulp temperature of the fruit then coming into the packinghouse would be 55 to 90 degrees. And, again, when the fruit is run over the line, we like to see--we estimate it would be 55 to 75 degrees because, again, the fruit are being held overnight and it's moderated.

After de-greening--and we de-green late-season Valencias; this would be in the months of August, early September--it would be 70 degrees Fahrenheit, approximately. The packinghouse temperatures during this period of time we estimate would be about 60 to 80 degrees Fahrenheit. Cold room temperatures would be identical. These conditions would be identical. And then if we move down into the water temperature, we estimate at 65 to 75 degrees Fahrenheit.

Fruit coming from the inland empire would be virtually the same, except the ambient here would be 65 to 100 degrees Fahrenheit, and we have fruit grown in the Coachella Valley, which is a very warm production area, and again it would be, we estimate, 65 to 100 degrees temperature. But these temperatures here would be approximately the same.

Now, I talked to the two representatives from California Day-Fresh and Perricone, and we talked about their conditions. Fruit temperature when the fruit is run over the juice plant line in the summer months would range in California Day-Fresh 60 degrees, approximately; Perricone, 60 to 65 degrees. In the winter--these should be reversed. Sorry. Sixty degrees because they hold their fruit in a cold room overnight versus 80 to 85 degrees for the Perricone plant. In the winter months, we're talking 50 degrees versus about 60 to 65 degrees.

Plant temperature here you can see in the winter months would be 60 to 65 degrees for California Day-Fresh versus 50 to 55, and in the summer, 75 to 80 versus about 65 to 75. The difference is because of an elevational difference. California Day-Fresh is in Glendora. Perricone Juice Plant is in Beaumont, which is a higher elevation, about--I'm guessing about 1,500 feet.

The water temperature here in the summer would be about 75 degrees versus 65 to 70, and in the winter months, again, about 50 to 55.

So the temperature differentials here, we're talking probably at a maximum temperature differential, and, again, the fruit is only exposed to water for relatively

short periods of time, would be a maximum of about 20 degrees Fahrenheit, maximum temperature differential.

MS. OLIVER: Thank you very much.

DR. ARPAIA: You're welcome.

MS. OLIVER: What I'd like to do now is open up to the Committee for, you know, at least 20 minutes to see if there are any comments people want to make or discussion you want to make before I go around and poll the group, because some of you may think there are some things you want to say before that. So let me ask that, and if anyone has anything, we'll put--you know, I'll call on you.

Don't think so. Okay. With that, I'm going to start on this side since people are leaving early, unless, Nancy--because Cathy's leaving and there are a number of people on this side who are going to leave early, so I'll start going around this way.

What I'd like is for the Committee to respond, first I'll go around on internalization and survival of pathogens. Cathy, what time are you staying until?

DR. DONNELLY: I've got leave probably at 2:00, and I apologize.

MS. OLIVER: Okay. Can I ask you then, before you leave, to be the first then to respond to both groups of questions? One is if you could respond on internalization and survival of pathogens and respond to the four at once, and then to respond to the application and measurement of the 5-log reduction standard and what your advice would be there. Thank you.

DR. DONNELLY: Thank you. I feel a little bit on the hot seat. I think based--and I'm really going to restrict my remarks to the scientific data that's been presented, and that is what we've been asked to do.

I think we've seen data that internalization of pathogens can occur under laboratory controlled conditions. Whether I've seen data that that's applicable to a field condition--

MS. OLIVER: Can you identify yourself?

DR. DONNELLY: I'm sorry. Cathy Donnelly, University of Vermont.

Do I think that such internalization is likely to result in a public health risk? I have not seen evidence that that's the case, and instead, I've seen compelling evidence that contamination is a result of post-process contamination that I think can be controlled. And, again, so that response to D, I think a HACCP program with proper verification and validation is a way to control risk.

In terms of the next set of questions, again, because we're dealing with citrus specifically, I think the 5-log reduction based on the scientific evidence that I've seen, starting with the fruit from the orchard, I think is an appropriate place to start. And, again, I think regarding Part B, questions 1 and 2, clearly the less time that the product has an opportunity to support the growth of pathogens, the safer the product. And so I think my answer to both of those questions are--again, I've seen data and, you know, John's work in the pilot HACCP program. I think that you can safely achieve the equivalent of a 5-log reduction through model HACCP programs like that which is being used in the fresh juice industry.

MS. OLIVER: Thank you.

Is there anyone else that's leaving fairly

shortly? Okay, Nancy?

MS. NAGLE: Nancy Nagle, Nagle Resources.

To keep this brief, I agree with what Cathy said. Those were the same answers I pretty much had for questions I, A, B, C, and D. Yes, it's theoretically possible that they could be there, but we didn't see evidence that there's really--in the current system that it's really going to happen. I don't believe that it's truly a public health risk, internalization of these organisms.

Hello? This isn't working? Okay.

And then as far as the second part, I think there are some issues that we heard about that the 5D reduction I believe should start at the point of receiving within the plant. There is one thing that I think we heard some--enough data about that we do think--and a few of us over here were discussing, and actually we have Mike's comments, too, to give you--that these things need to be linked in time, these reductions, that there can't be--we felt that the idea of having some culling and washing at a packinghouse and counting that and then shipping these fruit thousands of miles, or whatever, we don't think that's an appropriate--you have to start from when you receive it at the place where you're going to juice it.

We also felt that there was a problem of having the reduction and then putting the juice in a tanker and shipping the juice somewhere to another location. That also, we felt, presents somewhat of a problem.

We like the idea that--we do think that the 5D reduction can be effective, but it needs to be within the confines of the actual processing environment that is going to process and package that juice.

MS. OLIVER: Thank you very much.

Okay. Might I ask again if anyone else is going to be leaving fairly shortly, so we'll take those comments.

[No response.]

MS. OLIVER: Okay. If not, Bruce, can we start around the table with you then in order?

DR. TOMPKIN: Am I going to answer the whole sheet or just--

MS. OLIVER: I think if you could go with internalization, we'll go around on that, and then go the other way. It would be better for the record, I think.

DR. TOMPKIN: Okay. I'm Bruce Tompkin. Is it valid to assume there is no internal--no, I don't think that we can assume that. And certainly it is theoretically possible for internalization to occur. If it does theoretically, does represent a public health risk? I say no. And within USDA framework, what we work by in terms of significant hazards, it's a hazard which is not reasonably likely to occur in whole fruit or in the juice as a result of internalization. And if it does--so then that's the answer, if I have to answer the fourth, D.

MS. OLIVER: Thank you. Earl, if we could just go straight around?

It is possible under certain conditions to introduce pathogens into citrus fruits, but under normal circumstances, I do not think that poses a public health hazard.

On the second set of questions, I think the 5-log reduction is sufficient because--

MS. OLIVER: I think we are just going to go

around on internalization first and then come back. We are going to go back on the first set of questions.

DR. LONG: Okay, fine. Right.

I do not think it poses a public health risk.

MS. OLIVER: Dane?

DR. BERNARD: Thank you. Dane Bernard.

Internalization. I mean, theoretically, it is possible. That is what we have been shown. Does it happen commercially? Probably not. I think the conditions studied show that it is possible, but in my mind, the commercial conditions were distant enough from the laboratory conditions that it is an open question. I do not think at this point that I am ready to conclude that it is a commercial reality.

On the third question, if it is possible that such internalization is likely to result in a public health risk, again, it is an open question, but if you did have internalization from Dr. Miller's data, we did not see much in the way of growth. We got some growth if it was not in the juice itself, but even then, it was fairly limited. So that further tells me that if it is a rare event, then we are not likely to have significant levels of contamination.

However, if we are not correct on that assumption, the answer to D is obviously there are ways of addressing it, but it would involve applying some kill step to the juice itself.

Thank you.

MR. SEWARD: Skip Seward, McDonald's.

I would say under normal processing with choice grade or higher raw material that internalization is unlikely to occur, and that there is no public health risk associated with routine operations as described to me. To prevent that, it seems like you could very easily keep the temperature differential under control as a possible control step to help limit that potential.

MS. OLIVER: Peggy Neill?

DR. GROVES: I do not think people are answering Question D. I'm sorry, but they are talking around it. I do not think we are answering.

Dane, with all due respect, they were not talking about pasteurization of juice here. They are asking about if there are ways to prevent internalization.

MR. SEWARD: The only thing I would say, Michael, is that so far, everyone who has spoken said that they did not consider this to be a public health risk, and, therefore, that question starts out indicating that if you do believe it is a public health risk, are there ways to prevent that.

DR. GROVES: Okay.

DR. NEILL: Peggy Neill.

My observation is in terms of trying to answer the questions strictly as they are in the paper.

I do not think it is valid to assume that there is no internalization of these pathogens into citrus fruits. I think we have seen data to show that a set of conditions could be defined under which it could occur, and I do not know whether those conditions, when modified to approach those that occur in the real world, would result in the same findings.

I am probably most concerned about my answer to C. I do not know whether this internalization occurs in the

real world and as such represents a mechanism by which juice is contaminated.

I am very concerned about an interpretation of epidemiologic findings that says we are very limited in the number of outbreaks associated with juice and, therefore, because there have been so few cases associated with it, it really must not be a problem.

As Bala has spoken to and I in previous meetings have pointed out, our mechanism for associating a case with a mode of acquisition involving a food is very, very problematic when it is a low-level contamination that is very diffuse geographically and temporally. For that reason, my answer to C is I do not know.

My answer to D is probably somewhat similar to Skip's in that addressing that this is not about pasteurization, but is about the step of whether internalization of pathogens can be interrupted. I think unless we know the conditions under which it occurs in nature, if it occurs, we cannot talk about an intervention.

DR. ACHESON: David Acheson, New England Medical Center.

My answer to A is no. I do not think it is valid to assume that no internalization can occur. So, clearly, my answer to B is yes.

C, I am stumbling over the word "likely." Of that statement in C, it is the word "likely" that has got me thinking in terms of from the data I have heard presented today, and unfortunately I was not here yesterday, I do not get the sense that this is likely to occur, but I do have some element of concern that if as few as ten 0157 organisms were to make it inside a piece of fruit, that theoretically could be a lethal dose in a susceptible child.

In terms of D, the only thing I would think of is that I would agree with Skip. It seems that temperature equilibration would be a critical issue here, and if that was addressed, that may solve the problem.

DR. KVENBERG: John Kvenberg, FDA.

My response is to Question A, no, you cannot make that assumption. Therefore, logically, the extension to B would be theoretically possible, yes.

Under C, for internalization of pathogens to the key phrase "internalization likely," I say it is unlikely given the information I heard relative to temperature data and the differentials, with the caveat that you have to assume that risk reduction is taking place as we heard it relative to good agriculture, good manufacturing practices, and the application of HACCP-based programs.

Relative to Question D, which the core of it is are there techniques to assure the internalization of pathogens not going to a kill step or a reduction, but rather an exclusion through temperature differentials, yes, I think the key to the question that they have discussed here is temperature gradient plays a major role in risk reduction relative to the internalization question.

That is it.

DR. DOORES: Stephanie Doores, Penn State.

My answer to A is no, but, B, theoretically, it is possible.

In terms of Question C, where we are talking about pathogens in citrus fruit, we have primarily focussed on bacterial pathogens, but I do not know if there is any data

out there to suggest that other organisms could present a health risk, such as viruses or parasites in this type of a situation where we are talking about internalization.

So I guess in that sense, it is probably theoretically possible that there might be some other situations which we have not been alerted to or not specifically looked for at this time.

In terms of the techniques, to assure that internalization of pathogen does not occur, I am not sure that the techniques out there are necessarily practical at this point or whether it requires some other intervention strategy that would not be at the fruit level, but further on down the line.

DR. DOYLE: I am Mike Doyle with the University of Georgia.

I would say no to the first question.

Second, yes, it is theoretically possible that pathogens can get into fruit juice. I believe what Art Miller has done is valid.

C, I am not convinced that in reality that intact citrus fruits would be internalized normally, under normal conditions, but I do have a concern about fruit that may be punctured or split or not intact, and I consider that to be a public health risk. So the answer to that is to avoid fruit that is split, punctured, or not intact.

DR. ENGELJOHN: Dan Engeljohn with USDA.

The answer to the first question, I would say no.

For the second question, I would say yes. It is theoretically possible.

For C, I have concerns about the most vulnerable population, but I think the reality is I do not believe it to be a problem at this time based on what I have heard.

Then, for D, aside from temperature, I do not know what other interventions would work. I do not know enough about it yet.

DR. LIANG: Art Liang, CDC.

IA, no. IB, yes. IC, no. ID, not applicable.

LTC SEVERIN: Scott Severin, DOD.

IA, I also would say is no. I do believe it is theoretically possible. From the standpoint of a public health risk, probably not, but due to the limitations on infective dose, I could not rule that out totally. D, I would say the only thing we are aware of right now would be temperature control.

MR. EKLUND: Mel Eklund.

For A, I would say no. B, based upon the data that we have heard today, I would say theoretically possible, and C, if it does occur, I think it would be very infrequent. I think Mike Doyle had a good comment to avoid fruits that are damaged by various means. That could be greatly avoided. So I do not think that C would be in practical conditions probably a major concern.

DR. ANDERS: Jim Anders, North Dakota Health Department.

A is no, but I hope we are not taking that to mean that we are saying yes if we reverse that. I do not think we really know. It certainly is possible under B. It is theoretically possible. I think it is quite unlikely. C, I do not think it is a public health risk, and D, I guess temperature control, and I would second on damaged fruit, obviously.

DR. MORALES: Roberta Morales, Research Triangle Institute.

A, I would say no, not valid. There is no internalization. B, theoretically, yes, it is possible. C, the data may not represent what is really there in terms of public health, and I do not feel that there is really good prevalence data on pathogens of public health concern. However, I would also tend to say that I think it is not highly likely that this is a public health risk. So D, to me, becomes irrelevant in that case, but if I was to propose an answer, I would say yes, I believe there are ways that can minimize that risk.

DR. SWAMINATHAN: Bala Swaminathan, CDC.

The answer to A is no, but I would go along with the caution that was raised by Jim Anders that we do not immediately assume that there is internalization of pathogens into citrus fruits. In fact, we have very little data to support either way. For B, the answer is yes. C, theoretically, it is possible, but the chance probability is very, very low, and, therefore, D is really a moot point.

DR. BUCHANAN: Bob Buchanan, FDA.

My answers to A would be no, it is not appropriate to assume that no internalization occurs. B, based on both the research data presented and the literature on plant pathogens, yes, it is theoretically possible. C, it would appear to be a low probability event, but the potential is high enough where it would have to be considered in a hazard analysis in developing a HACCP program, particularly in comparison to a process that started after juice is made or a process that was limited just to surface inactivation.

I think that there are techniques available. Certainly, there were some in the research that was presented here, though I did not hear much data in terms of controlling insects and other types of market defects, other than careful selection and culling of fruit that had any kind of a blemish or a puncture or a cut or whatever.

Thank you.

DR. SPERBER: I am Bill Sperber with Cargill.

I think Questions A and B are not very useful for the agency because they are phrased such that the logical answers can only be no and yes, respectively. Question C, likely not a public health risk. Question D, maybe there is a control measure. There is one possible measure that has not been mentioned, and that is if the FMC extractor is used, the core removal is essentially an aseptic process. So, if there had been internalization, that could be removed during the extraction of the juice.

DR. DICKSON: Jim Dickson, Iowa State University.

As previously pointed out, the answers to A and B can almost only be no, it is not valid to assume there is no internalization, and, B, yes, it is theoretically possible.

Regarding the result in a public health risk using the definition of "hazard," reasonably likely to occur, no, this is not reasonably likely to occur.

DR. GROVES: Mike Groves.

A, no. B, yes. C, no public health risk. That makes D moot, but the answer to that is probably there are ways.

DR. O'BRIEN: Alison O'Brien.

A, no. B, yes. C, reading it as the question is stated, if there is internalization, if it is possible, is

it likely to result in a public health risk, I think it could. I am not willing to say no, flat out. Therefore, I have to answer D, and one other point which was brought up by Mike Doyle, the use of the type of fruit that is actually used, I would say at least choice fruit be used. It was not clear to me that was always the case.

DR. KOBAYASHI: John Kobayashi, Washington State Health Department.

My answer for A is no. B is yes. My answer for C is unknown, although it appears to me on the experimental level that the answer is obtainable with perhaps some cooperation between the various studies and the investigators that are doing the experimental work. Epidemiologically, I think that it will be very hard to identify internalization as the source of an outbreak versus other causes of contamination, although I will keep that question in mind when we have our next outbreak.

I think because C is unknown, my answer to D is unknown, but one comment I have on this Question C, is internalization likely to result in public health risk, I guess there is a certain interpretation going on in the word "likely," and I think that one way of looking at that is that the Odwalla outbreak and the Sun Orchards' outbreak could be considered unlikely events considering the amount of orange juice distributed in the United States, but I think that that is a publicly unacceptable occurrence of unlikely events.

DR. JAHNCKE: Mike Jahncke, Virginia Tech.

My answer to Question A is no.

Is it theoretically possible? Yes. I think that the data and the experiments conducted by FDA indicate that it is theoretically possible. I think that the information and the data presented in these last 2 days indicate that it is unlikely under current industry practices. Although I think some data is being collected, additional data on some of the initial conditions of the fruit, of the citrus fruit on the tree and as it enters into the packing plant needs to be collected.

For Question C, is internalization likely to result in public health risk, I am going to tie this in. I think Mike Doyle hit upon what I found was a very important aspect. I agree that if you have a fruit that is in good condition, choice, the likelihood of internalization of pathogens is unlikely. Therefore, the risk to public health by that definition is unlikely, but if you have a damaged fruit, a cut fruit, something like that, the likelihood of internalization of a pathogen goes up. As David was indicating, with the 10 cells of 0157:H7, it can result in a significant public health risk.

In that regard, when we get to Section D, there was a lot of discussion in the last 2 days how effective it was for manual culling of these citrus fruits as they go down the line. Being involved not necessarily with the citrus industry, but with the seafood industry and seeing the product go down the product line, I assume that during the citrus industry, the product moves on pretty quickly.

Yesterday, as one of the presenters indicated, if you take a look at the number of errors that are associated with an operation, 88 percent of it can be associated with human error. I am not convinced that manual culling of these citrus fruits is 100-percent effective. You are going

to be getting some defective fruits, some damaged fruit coming through that may have pathogens that have been internalized.

How do you address this? A couple of suggestions, perhaps. In one of the presentations in California, they are still immersing some of this fruit that is used for fresh juice. I think what ought to be done is adapt the Florida model where there is no immersion of the fruit. It is all washed and brushed.

Another potential method--and I do not want to mix apples and oranges, but I think it is appropriate at this time--in the apple industry, there is a laser technique that is used for grading apples, and I think it is also used for looking at damages, damage on apples. Maybe something like that could be incorporated into that production line, have a laser that would go across your fruit, identify potential damage on the fruit. That may be one way of a technique that can address that issue.

MR. SVEUM: My name is Bill Sveum, Campbell Soup Company.

My answer to A is no, and, yes, it is theoretically possible in B. I do not believe there is a public health hazard with this particular issue, and with D, it would be no, but if there was the theoretical possibility, temperature control, as we discussed, fruit quality, as was referred to here by Mike, vision systems could be used over people on these lines to cull out fruit, redundant systems, and you could take care of your fruit quality that way.

DR. RUSSELL: I am Leon Russell, Texas A&M University.

IA, no. IB, theoretically possible, yes. C, I am also hung up on the word "likely," and "likely" is a qualitative term. You are trying to answer that with a public health risk, which should be quantitative. Really, I had trouble measuring that. So I would rather err on the safe side like Dr. Acheson. You have got some young kids out there that may be exposed to a small does. I would rather err on that side, although I think it is very unlikely under present conditions, the commercial way to handle things. So I would say. The last one, I would say mandatory HACCP and include the things that Mike and Bill just mentioned, include the latest technology as it goes along, but mandatory HACCP including temperature control and sanitizing control, much better methodology in the microbial analysis and end-point testing.

Thank you.

MS. OLIVER: Thank you very much.

What I would like to do now is to have each committee member address the question under Application and Measurement of the 5-Log Reduction Standard that you have been handed.

Leon, I would like to start around this side first, just because of the number of people who will be leaving earlier and it will be very close to that time.

Do we have Mike Robach's comments?

DR. DOORES: Nancy partially gave his.

MS. OLIVER: His comments all deal with the next question that we have. So let me read them into the record first.

This is from Mike Robach. I want to be here this afternoon, but here are my comments. For juice squeezed and packaged on site, a 5D process under HACCP is acceptable, 5D from fruit receipt. Juice expressed in one plant and bulk-transported to another location should be pasteurized or subjected to a 5D process under HACCP. The problem is one of GMPs, SSOPs, and loss of control during shipping. There simply is not any evidence indicating that juice product from fresh fruit and packaged in the same establishment is harmful to public health, and that is Mike Robach.

DR. RUSSELL: Leon Russell, Texas A&M University.

At the point of the 5-log reduction being at the juice plant upon receiving, rather than after washing and cleaning, and I think it ought to be just before it is packaged that would be the end point.

MS. OLIVER: Can you repeat that? I'm sorry.

DR. RUSSELL: I jumped from A down to B-2. The last sampling should be done actually after it is packaged, taken out of the package sample to see what the reduction is in the final product as it leaves the juice plant.

MR. SVEUM: My name is Bill Sveum, Campbell Soup Company.

I believe this 5D-log reduction should begin at the point of receipt in the processing facility, using the steps that have been described and that they be linked tightly together. I have a very large concern if juice is inter-plant shipped through trucks, if it was brought in bulk, I would require a pasteurization on that because it is not done on site.

DR. JAHNCKE: Mike Jahncke, Virginia Tech.

I would agree with the previous two. I think that the 5-log reduction step should take place at the time of receipt, and I also agree, as Mike's comments and the others, much more control. HACCP would be much more effective if everything is done within the plant. When you start shipping the juice from one plant to another, I think it will cause public health problems, and I do agree that that product should be pasteurized.

DR. KOBAYASHI: John Kobayashi, Washington State Department of Health.

I agree with the previous comments on Question A that 5-log reduction should be measured for time of receipt, although in addition, there appears to me to be a question of should fruit be cleaned and culled before measurement of 5-log reduction has begun. My answer to that question is yes, also.

Regarding Question B on 1, would using cumulative steps that are separated in time and location impact a processor's ability to achieve and deliver a 5-log reduction, my answer to that is yes, or I think restating that in the way that others are saying that it is a problem with regards to transport of product and having control measures occur in various locations.

My answer to the Question B-2, can the safety achieved by the 5-log reduction be maintained consistently if a processor does not package product immediately after attaining the 5-log reduction, answering that question as it is asked, my answer is yes.

The question that I think is more important, though, is should that be allowed, and I do not have an answer to that.

DR. O'BRIEN: My answer to A is that we should start as the fruit enters the plant, and B-1, I think that, yes, there would be an impact on the 5-log reduction if there was a separation in time and location as the steps are being monitored. I agree that unpasteurized or fresh fruit should not be stored in big bulk containers, and it should be pasteurized under those circumstances if it is going to be transported like that.

II-B, I do not think the safety can be achieved. My answer is no, by a 5-log reduction, without testing the product package immediately.

DR. GROVES: Mike Groves.

A, at what point in the production process should the process being measurement, I say at receipt. Part two of that, for example, should fruit be cleaned and culled before the measure, the answer, of course, is no.

B, are there limits within which the 5-log reduction must be accomplished, yes. B-1, would using cumulative steps that are separated in time and location impact, yes. Can the safety be achieved without packaging immediately, I do not know. Maybe.

DR. DICKSON: Jim Dickson, Iowa State University.

I would say for Part A that the 5-log reduction should be measured at the beginning of receipt of the fruit. I am reluctant to dismiss cleaning and culling because those are effective measures of preventing contamination in the finished product, and personally, I would rather prevent contamination of the finished product than try to clean it up later. So I think cleaning and culling are very important preventive measures in this whole process.

Cumulative steps could be effective. It would depend on the individual step. Question 2 of Part B, the safety could be achieved if the product was not packaged immediately, but clearly that would put the product into a different category and would probably require some special handling circumstances.

DR. SPERBER: I am Bill Sperber from Cargill.

Question A has really two questions in it. The first question is more of a HACCP-type question, and the second question is kind of a GMP question. I point that out only to make the point that during this past day, there has been a lot of distortion of the concept of HACCP, and a lot of people are confusing GMP procedures with the HACCP program. So it is important for our continuing discussion.

A-1, if a 5-log pathogen reduction is required, it has got to be done in a HACCP context, and it would have to be implemented after juice extraction. It starts with the juice, not with the fruit.

B, cleaning and culling are GMP steps, not part of your 5-log reduction. If they are sufficient to reduce the hazard or eliminate the hazard, we do not need to be talking about 5-log reductions or HACCP. We can control the problem simply by enforcing existing GMPs.

You cannot take cumulative steps and apply them at different times and different geographies and get full credit.

Two, the answer is no to B-2.

DR. BUCHANAN: Bob Buchanan, Food and Drug Administration.

II-A, considering the comments that I have heard around the table about the critical nature of starting with

sound fruit, I would say that you would start counting the 5D reduction after culling, and since culling is almost impossible to do without some initial cleaning, I would suggest after cleaning and culling would be the appropriate start point for the 5D.

I have concerns with any process that the longer and more complex it is, the easier it is for failures to occur. While I think that cumulative steps can be effective, I think that the amount of time between those steps need to be limited, and I have very significant concerns about locations, particularly if the juice has been expressed and is moving from one location to another. I would have some real concerns about it being recontaminated at that point.

Thank you.

DR. SWAMINATHAN: Bala Swaminathan, CDC.

The answer for A is it should start at the point of receiving in the processing plant. The cleaning and culling should be mandatory requirements for the oranges or on ingredients that come into the processing plant for fresh citrus juice.

Are there limits within which the 5-log reduction must be accomplished? Definitely yes. Under B-1, yes, it would have a very adverse impact if the steps are separated in time and location, and for B-2, the answer is no.

DR. MORALES: Roberta Morales, Research Triangle Institute.

For A, I would say at the point of receipt. For B, are there limits, yes, there are. My answers for both 1 and 2 are going to be related in that if the cumulative steps are separated in time and location, the more that separation is in the cumulative steps, the higher the likelihood of a failure occurring. So, likewise, the longer the time between when the 5-log reduction is maintained and when that product is packaged, also the higher the likelihood of a failure occurring. There should be limits, and they should be specified even more stringently if there are going to be spatial and temporal differences.

DR. ANDERS: Jim Anders, North Dakota Health Department.

A, I believe that the 5-log reduction should be after the fruit has been cleaned and culled. That is when it should start.

Are there limits? There certainly are. With using cumulative steps that are separated in time, I agree that that should be limited certainly on how much time it takes and in between each step, and I have a serious concern about a separate location. I guess I would have real problems with tankers and that type of thing.

Can the safety be achieved? I do not think we have that evidence, one way or the other, there.

MR. EKLUND: Mel Eklund.

On A, I would say yes, that the 5-log reduction should be at the receipt of the product at the plant, and it must be done in conjunction with the HACCP plans within the plant.

For B-1, I would say yes, if they are done consecutively within the plant, and as other speakers have said, if there is a delay of time and maybe of an area, then I would say that part of the answer would be no. For 2, I would say no.

LTC SEVERIN: Scott Severin, DOD.

For the answer to A, I would say after cleaning and culling is when you should start your 5-log reduction. From the standpoint of limits, I feel that as long as time is minimal between steps, you cannot have cumulative 5-log reduction. I do not feel you can have a 5-log reduction if transportation is involved in another location.

I also feel strongly that there should still be a microbiological testing criteria following the attainment of your 5-log reduction just to verify that you have achieved that.

Thank you.

DR. LIANG: Art Liang, CDC.

II-A, after cleaning and culling. II-B, yes, there are limits. I share the same concerns about steps separated by time, location, or management, and 2, I do not know.

DR. ENGELJOHN: Dan Engeljohn with USDA.

For A, I would say at receipt after cleaning and culling. For B, I think yes, there are ways or there are interventions that need to be there, but for 1, I would say no, I think it can be controlled and validated if there is no growth. Then, for 2, I think, yes, if it is controlled and validated for no growth and no cross-contamination or recontamination.

DR. DOYLE: Mike Doyle, University of Georgia.

For II-A, I think it is important that we consider the cleaning and the culling as far as good manufacturing practices and do not include that as part of the 5-log reduction. That should all begin after the cleaning and culling.

I would encourage the industry to look harder at the surface steam pasteurization process because the little work we did no that, if there were splits or holes in the fruit, the inside of the fruit heated up and it got quite hot. I think it almost pasteurized that juice within the orange. So, if there were culls that got through, there may be a safety factor built in there, but you need to research that out more thoroughly. I think that could be a key critical control point for you.

In Section II-B, yes, I do think there needs to be limits within the 5-log reduction. Relative to the cumulative steps being separated in time, I agree with what has been said. It is a real problem to transport juice that has been processed somewhere else and assume that that 5-log reduction is still good.

I think you have got to start all over, and I would not give you any credit for juice that was transported through the plant.

Then, for II-B-2, can the safety achieved by the 5-log reduction be maintained consistently if a processor does not package product immediately after attaining a 5-log reduction, well, I believe you could do that. You would have to document it, but if you had aseptic conditions for holding the juice, I believe you could do that safely. I think the milk industry has big old silos where they put their pasteurized milk in and hold it there until they can bottle it. They do not do it immediately after pasteurization.

So I think it is reasonable to come up with an approach and especially if you all come up with testing

protocol for a critical control point. You are not going to get those results back in 5 minutes. You are going to have to probably hold that juice for a day or two. So you have got to come up with some way of holding that juice safely after processing. So you are going to have to think that one through.

DR. DOORES: Stephanie Doores, Penn State University.

For Question 1, I favor measuring the log reduction after cleaning and culling. I think if you do it before that time, you are achieving part of the reduction due to a dilution effect, rather than elimination of a problem, and I am not in favor of diluting out any potential pathogen load there due to the fact that some outbreaks of foodborne illness can result from only a few organisms.

In Question B-1, I think that if the juice leaves the particular location, again, all bets are off. I think you need to restart the 5-log reduction process there. If it is separated in time, I would like to know what that time is and have that defined.

I would also in B-2 like to know for what particular reasons the product is not being packaged immediately after processing, why that would or would not be done, but I think I concur with what Mike says, that we do have a history with other products under defined conditions.

Furthermore, I would like to add that I am very concerned that whatever organisms are chosen for the 5-log reduction, be they pathogens or indicator organisms for those pathogens, that the methods that are used to assess that reduction are specific for orange juice and appropriate provisions have taken into account oranges and their intrinsic and extrinsic parameters that may lead to erroneous results and perhaps estimation of a reduction when it is lack of recovery from the organisms, so things like terpinols in the orange oil that might be present there or any other Ph effects that those methods take into account, those kinds of things that can interfere with estimation of the reduction.

DR. KVENBERG: This is John Kvenberg, Food and Drug Administration.

Regarding II-A, my answer is that the point of the account for the 5-log reduction must be at the point where the juice is actually processed.

I agree with other statements relative to culling and cleaning. I feel very strongly that this ought to be a mandatory point, but it is not a critical control point. It is prior to a critical control point and, therefore, is not part of the 5D process.

However, this should not be confused with the flow diagram of a HACCP program, wherein the culling process may occur downstream from the initial point of entry into the plant. You may recall that high pressure does aid in sorting out and accentuating the fruit for the culling. So I am saying that the 5-log should begin after the culling process, as others have said, on through to the end of the process.

Relative to II-B, are there limits to which the reduction must be accomplished, I certainly agree with other statements relative to the cumulative steps being separated in time and location, are highly problematic, and lend themselves to recontamination problems. This is a severe

problem that negates the 5-log reduction idea that the committee originally proposed.

Relative to B-2, can the safety achieved by the 5-log reduction be maintained consistently if a processor does not package the product immediately prior to the 5-log, ideally if the kill step were applied to the juice, there is no doubt with mechanical measurement that this is achieved. Therefore, if there is not a full 5-log applied to the juice, then it may be prudent to consider product testing, as was suggested by the committee, to assure that the process that was applied did not result in a recontamination of the product.

Thank you.

DR. ACHESON: David Acheson.

II-A, one piece of data that I was not made aware of--maybe this was discussed more yesterday--was the total pathogen load on this fruit at the point at which it arrives in the plant. I want to try to separate "begin to measure attainment" as opposed to "begin to reduce the pathogen load." The question says "begin to measure attainment," and to me, just from a purely basic science principle, the further down the line you begin to generate your 5-log reduction, the better you are, but that is a theoretic argument.

So I agree with Mike that a substantial cleaning and then you begin to look for your 5-log reduction would be appropriate, but I would like to know how many bugs are on that to begin with.

II-B, obviously, clearly the transport issues are important. I would have thought with appropriate monitoring, this could be undertaken safely, but we cannot make any assumptions.

The second part of B, theoretically, yes, I would have thought that this could be maintained consistently, but, again, I did not see any data to suggest that this has been done, can be done, but, empirically, I would just feel that it is of limited likelihood that it could be attained without some major steps.

Thank you.

DR. NEILL: Peggy Neill.

With the assumption and understanding from the previous observations that cleaning and culling is a GMP, I, therefore, think that the answer to A for my response would be that measurement would begin after the fruit has been cleaned and culled.

For B, I think that there are limits, although I do not yet know that we would be able to define them in terms of time and mileage, be they hours or metric system or what.

For No. 1, using cumulative steps, I think it seems reasonable from the totality of the data that we have cogitated on before the meeting and for the last day or so that cumulative steps that are separated in time and location will impact the processor's ability, unless those steps have clearly been shown to be under the processor's control and for which there would then be an adequate track record for measuring that control.

For No. 2, whether safety could be consistently achieved, I think the key word was "consistently," and operating on the principle of Murphy's law, my answer to that then would be no. I do not think it can be maintained

consistently.

MR. SEWARD: Skip Seward.

The first question in Point A, I would believe, like everyone else, that it is at the point of receipt into the plant, and my answers for all the other questions are yes.

DR. BERNARD: Dane Bernard.

Let me first say there was a larger question on the adequacy of the 5-log. I personally have had no problem with 5-log as the target as long as it is understood that the target was identified to produce a finished product that had essentially the target that was in the proposed rule which was basically reasonable certainty of no pathogens in the finished product. So I hope we do not walk out of here envisioning that 5-logs means you can accomplish--prove that you started with 7 and end with 2 and we think that is a safe product. That was never the intent.

So, with that caveat in mind, should fruit be cleaned and culled, I think we have already heard many times that that appears to be a very vital part of putting into the process fruit of quality, good quality, that would have a potential of low prevalence. So I think the 5-log should begin after cleaning and culling.

Are there limits within 5-log reduction that must be accomplished? I have several limits. First of all, the scientific rigor with which one proves their point that they have met the performance criteria, I think we have to hold a fairly stringent yardstick to any process that claims to achieve that log reduction.

I agree with the previous comments in terms of keeping the time frame between steps at a minimum. Rigorous sanitation in the operation appears to be very important to all of this, and there have also been several interventions mentioning the necessity of microbiological testing as a continuing verification of the effectiveness of the application in the 5-log process.

On B-1, would cumulative steps separated in time and location impact the ability to achieve and deliver 5-log, I think we have seen beyond probably any doubt that there is an impact, and I would agree with previous speakers who have mentioned that they are very uncomfortable with seeing large separations in time and space in terms of the delivery of the 5-log. So I am very uncomfortable with that as well.

B-2, can the safety achieved by a 5-log reduction be maintained consistently? I would agree with Peggy that any separation between achieving 5-log and packaging raises the possibility of mistakes, not counting Mike Doyle's caveat regarding aseptic processing. If someone can prove your point, fine, but if you are not willing to spend the money to put in aseptic equipment and maintain it and run it aseptically, then I would suggest that we go right to packaging after delivery of the process.

Madam Chairman, are we going to have further comments after answering the questions? Because I really think we have not addressed the cause of the more recent outbreaks with any of the questions that we have answered.

MS. OLIVER: I think the questions that we had were basically the two questions, and I have some questions of clarification on micro-testing. If the committee feels they need to make some additional comments, I will allow

that, but I do not want to go too far beyond.

DR. LONG: Earl Long, CDC.

On II-A, I think the measurement should begin at the point of entry. B-1, yes, and B-2, no.

DR. TOMPKIN: This is Bruce Tompkin from ConAgra.

I think the 5-log reduction that we have had in place since '96 has been effective in bringing about change. The question, is it adequate, the comments about whether or not--well, first, the question--I believe that the 5D process should be from the whole fruit upon receipt at the plant. The difference between whether it should be before or after culling is like adding on another 2-log reduction. Really, are we talking about a 5-log reduction or a 7- or 8-log reduction?

As we went through the process yesterday, I am trying to put myself in the place of a processor and trying to live with what this committee is going to require. I am trying to see whether I will be able to produce a fresh juice with a 5-log reduction beginning after cleaning, culling, and washing.

You might recall yesterday when we went through our little HACCP validation here that we picked up about a 3-log reduction just through those steps. Those were very important steps. So the question is: Do we need additional kill and to what degree do we need that kill?

I think the system that is in place is working. It is a matter of bringing everyone else up to the level where they are at this point in time.

As for B-1, then I would say yes. The process should occur on site from raw fruit to the juice and avoid incoming tankers.

With regard to immediate packaging, well, certainly it is possible to hold product over some period of time after creating the juice. It is really a matter of recontamination, and that is a manageable risk.

MS. OLIVER: I have a couple of questions.

Leon, Bill, and Mike, I did not hear your response to Part 2 of Question A as should the fruit be cleaned and culled before measurement of the 5-log reduction has begun. I might have missed it.

DR. RUSSELL: Leon Russell.

It should begin at receipt of the plant before cleaning and culling.

MR. SVEUM: Bill Sveum.

The same point.

DR. JAHNCKE: Mike Jahncke.

At the time of receipt.

MS. OLIVER: I had another question of clarification. Several of you mentioned testing in various ways, John, Mike Doyle, Dane, and someone on this side. I was wondering if you could clarify what type of testing you are talking about.

DR. BERNARD: Dane Bernard.

Let me also ask, if I could, because there is some confusion, at least now in my mind, regarding the cull step, cleaning and culling. I viewed that more as a receipt step rather than what was explained as the wash step, which I think is what Bruce was talking about in terms of claiming some log reduction. So I was talking my version of cleaning and culling, if I understood the presentations, is more a rough clean and getting out and then beginning to count the

5-log.

So I think that we have had several people answer the question yes and several answer no, when I think they were thinking the same way. So I would like to have a clarification on that.

DR. GROVES: I agree with Dane. This is Mike Groves.

Do people realize it is after the cleaning and culling, the people who have answered this? Were they saying we want pasteurization? Because it seems to me that is what we are talking about. Getting a 5-log reduction following the cleaning and washing step, if it is the rigorous cleaning and washing that I saw described, we are talking about not getting there unless you have pasteurization. Is that what people that answered that question meant?

MS. OLIVER: Let me go around and ask individuals one of two ways.

Go ahead, Bob. What is your comment?

DR. BUCHANAN: Bob Buchanan, FDA.

I guess my comment on initial cleaning and culling is you get rid of the big chunks. There are some obvious fruit that just should not be in there, and while I am not considering this as a rigorous cleaning step, often these blemishes are not available until after you can give them at least an initial rinse. So my thought was a gross separation of the bad fruit out, and if necessary, some kind of reasonable initial cleaning of the product so you can see the defective fruit, but then to start it after which with your rigorous washing and sanitizing steps.

Oh, I would assume that somewhere after the rigorous washing and sanitizing steps, there would be a subsequent final call to look for new defects that have come out as a result of high-pressure cleaning, et cetera.

DR. O'BRIEN: Alison O'Brien, Uniform Services.

The reason I voted for receipt, starting at the level of receipt, was I do not think they can document later on that they have had a 5-log reduction. From what I heard about what the level of organisms, just plain old coli kind of bugs, were on the fruit and if we forced the producers into the position where there is no possible way of demonstrating 5-log reduction, I think that is what Mike means by pasteurization, unless I misunderstood what people said about the level of organisms on oranges.

MS. OLIVER: What I Bob say is the cleaning and culling that we are talking about in the question is basically your gross cleaning and culling to start with as opposed to going through your rigorous washing. What I need to do is be sure that everybody was answering the question in that way as they went around.

So can I go around the group and ask?

Go ahead.

DR. GROVES: We had better define carefully.

MS. OLIVER: Okay. Bob, I will ask you to define "carefully."

DR. BUCHANAN: My definition would be an initial rinsing or washing of the fruit so that you can take a rapid assessment of the quality of the fruit to see that it is in, as we described, choice or first-run as opposed to processing, separate out the processing, then begin starting with choice or better, start the process then through

whatever sanitation, steam treatments, whatever, to get your 5D, but it would be to get those with obvious gross defects out of the pool of fruit before you start the process. That is, start your process with choice or better fruit.

DR. O'BRIEN: Alison O'Brien.

Let me start, then. That was my understanding that we were starting with a particular kind of fruit, and most of the time, it is at least choice. I am hoping that it would not be anything else but that. If we start with that, then we do the 5-log reduction from there. That is the way I was voting.

MS. OLIVER: So what I hear as an assumption is basically starting with choice fruit coming in and then seeing that is the cleaning-and-culling answer that people were giving in that response. I would ask, can you go around and tell me if it is in that context that you gave your response, choice clean fruit?

Go ahead.

DR. GROVES: I would think what you would like people to answer is at what step do you think they should start the 5-log reduction, at immediate receipt, when it has been given some sort of brief culling and cleaning, or after the rigorous wash process, to make it very clear what people are voting for.

MS. OLIVER: Why don't we take a 15-minute break so that I can clarify the question, get it on a piece of a paper, and we can make sure that everyone has it because of the confusion.

The other thing is that there are brownies upstairs.

[Recess taken from 3:07 p.m. to 3:34 p.m.]

DR. BUCHANAN: Hi. This is Bob Buchanan from FDA.

As we went through and discussed what different people were trying to refer to at different steps, we came up with the following flow diagram to try and get a handle on what we were referring to in terms of cleaning and culling.

The concept that was seen here was to get something equivalent to the separation of oranges that we see in the packing house into what we referred to here, second quality or oranges that would go to further processing or into processed products versus high quality which in California, I guess, was broken into two areas. It was first run and choice.

The equivalent on this side, going directly from the orchard or cold storage, to a juicer, a fresh juicer, would be the equivalent of some sort of gross cull to get the classification to the equivalent of this, and it was thought that this would require some cursory washing in order to be able to see defects that allow a separation in the basis of quality and then some initial culling to get the processing quality of oranges segregated.

This was from that point on done under one roof. That would be the rest of the steps that are currently used in a fresh juice operation, which would include the normal washing, intensive washing and brushing, sanitizing steps and a final culling and then juice formation.

At least the people over there are trying to put a definition behind cleaning the culling, and the thought was it would be getting the oranges that are going directly from the orchard or cold storage to a juicer to the equivalent of

the oranges that would be coming from a packing house into the final operation.

That is what we are using as a working definition now.

MS. OLIVER: Of cleaning and culling above the red line.

DR. BUCHANAN: Cleaning and culling above the red line.

MS. OLIVER: If I could ask the committee, then, once again, to respond to the question as to whether fruit should be cleaned and culled before measurement of the 5-log reduction has begun.

Dr. RUSSELL: May I ask a question, please? Leon Russell, Texas A&M.

Under one roof, does that begin where the red line is? In other words, the wash and cull is outside the building?

MS. OLIVER: Bob, as I understand it, where you have receipt at juicer and then under one roof, that that brief washing and culling could either occur at the processor or elsewhere, and so that it could all be under one roof and it could all be the juicer going down, right?

DR. BUCHANAN: It could all be under one roof. In the case of the packing house, it would be done somewhere else. The segregated oranges of the appropriate quality would be then shipped to the juicer.

MS. OLIVER: Bruce?

DR. TOMPKIN: This is Bruce Tompkin.

I just had a question relative to the use. Is there a wash step prior to culling that is typically used today? I do not know that I would put a wash step in before I cull. I would cull and then probably then begin to apply the wash so that you get rid of all the big junk first, and then it is a matter of where do you start at that point. It is a detail.

DR. BUCHANAN: This is Bob Buchanan from FDA.

We were at least told partially that it is hard to see defects in the oranges without some kind of initial cursory washing step.

DR. BUCHANAN: I would just ask you for confirmation of that.

MS. OLIVER: John?

DR. KVENBERG: This is not a snide comment, but let's call it a "grove" and not an "orchard."

This is John Kvenberg.

I think the important point is that you start at the grove and may or may not go to cold storage on this. The important point is at the red line, either outside the building or inside the building. We are looking at a pre-cull. That is correct, is it not? The pre-cull is before you begin the 5D under one roof. Is that what we are saying?

MS. OLIVER: John, who are you asking the question to?

DR. KVENBERG: Bob Buchanan.

DR. BUCHANAN: Yes. It is an initial segregation of the product into the quality of orange that we had expected to be introduced into the processing step and into the counter, what you need to start off with before you start counting the 5D.

DR. KVENBERG: Is the brief wash critical prior to gross cull, I guess was the point, because Bruce brought it up and that is when I got a little bit confused. Are we talking a wash necessary or a cull prior to starting the process?

MS. OLIVER: John?

MR. MARTINELLI: My name is John Martinelli. I am with Orchid Island Juice Company.

In the State of Florida and in California, if California is using packing-house quality of product and then you want to start the 5D, I think that is pretty much the process that is in place in California at this point in time.

In the State of Florida, we use field-run fruit that has no drops in it. There is not going to be dirt on it. There is not going to be heavy soil. There is not going to be all sorts of different defects. There is not going to be a lot of heavily decayed fruit.

The thing that we mostly grade for during the season is scratches in the surface of the skin and things like that.

As far as the brief wash in water and the gross cull, there is not a lot of rotten fruit in field-run fruit, and Florida's citrus crop, about 90 percent of it goes to processors like myself and Cargill and Tropicana. We use field-run fruit because Florida's crop is mostly used for processing. So there is not a lot of heavy decay. There is not a lot of heavy problems with the fruit as it comes in off of the trucks.

MS. OLIVER: Is there a basic culling when it comes in, a gross culling?

MS. SEXTON: Yes.

I am MaryGrace Sexton with Orchid Island Juice Company.

Theoretically, a damaged piece of fruit will not hang on the tree. So it is not going to get picked. It is not going to get into your packing house if you are using field-run fruit.

MS. RAINEY: Charlene Rainey from Nutrition Network.

I am from California, and there is a culling that happens prior to harvest in the field. They will go through and see damaged fruit on the tree, and they will pull that one or two days before harvest. So that, when you harvest the fruit from the tree, that you have good fruit. So there is an initial culling in the orchard.

DR. STROBOS: My name is Jur Strobos.

I think for purposes of trying to simplify the question, I have a diagram. I may have misunderstood, and this is a little bit of a simplification. There are some slight variations, but basically if it is going to go to the packing house, it will go from the grove to the packing house. There may or may not be a brief wash for leaves and stems and so forth. I think it may be relevant to some of the questions that are going on here, but there may or may not be some culling that takes place here.

In any event, there is a culling step that takes place here. Then the fruit goes through the processing, and then it will go into cold storage.

In California, if I understand it correctly, if that cold storage fruit is used for juicing, it will go from

there to the juicer, where it will go again through the same process. Again, it is a little bit of a simplification, but in Florida, basically we are talking about this process where it is going from the grove to the juicer. There may or may not be this step. There is a culling that takes place right here, and then it basically enters the plant, goes inside, really, and begins going through the sanitization, brush washing, extraction, and juice.

I think that may be easier because then the question becomes whether the 5D should start here or whether it should start here or whether it should start here. This may be helpful.

MS. OLIVER: The cull as I see it is before or after the brief wash, correct?

DR. STROBOS: Yes, and it would depend a lot on the particular operation.

MS. OLIVER: Basically, what FDA was saying, in Bob's diagram that he had up there before, was should it start after the cleaning and culling, including the brief wash and the culling up at the top before the sanitization, the brush wash, in either of those phases.

Correct, Bob?

DR. BUCHANAN: Yes. It appears that the two differences here are whether it starts at the point where you have on that diagram "juicer" or at the point where it says "sanitization and brush washing."

MS. OLIVER: Okay.

John?

DR. KVENBERG: John Kvenberg. Thank you.

I think the critical point here that I am aware of is a juicer may in Florida use California fruit or in California may use Florida fruit or may use other things. There is no State boundaries associated with processing this.

If it is coming from storage or cold storage, two things can occur. The fruit can get damaged in transit in the truck or it can deteriorate in cold storage. I think what we were trying to say on that diagram, that I was, that the juicer is looking at a pre-cull, and I am not clear whether there needs to be a wash or not, but there is no guarantee from the grove to the juicer through the packing house or its own cold storage operation really is going through a pre-cull. I think that was what in my mind we were saying. Prior to starting the 5D reduction process within the juicer plant, you need to have sound fruit to begin. That is all, but the count starts in the plant with that juicer. You are not counting the 5D process coming out of cold storage either within the juicer's facility or in the packer's cold storage.

DR. DICKSON: Jim Dickson from Iowa State.

It sounds like, John--and at least I am getting confused on this cull issue--it sounds like this pre-cull to me is occurring during the harvesting. Is that not correct?

DR. KVENBERG: May I respond?

DR. DICKSON: Please.

DR. KVENBERG: Not in my mind. Maybe we should get some clarification.

DR. DICKSON: Okay.

DR. KVENBERG: In clarification, the juicer should be responsible prior to starting it. That is how I responded.

DR. DICKSON: Right, but there is a selection step harvest.

DR. KVENBERG: Granted.

DR. DICKSON: That is all I was trying to clarify, John. Thank you.

DR. KVENBERG: Yes, but the point is that the culling process is the responsibility of the juicer.

DR. DICKSON: Right.

MR. BARNHORN: I know we keep going back to Florida and California, but we have a process flow which is a little different. I want to make sure that it is not monolithic in understanding that.

MS. OLIVER: I agree, but I think that the point does not matter. It is just us trying to get a clarification on where we are talking about.

MR. BARNHORN: Let me just make sure. We receive packing house fruit which has been pre-graded, pre-culled, waxed, washed, sanitized.

MS. OLIVER: Yes, that is up there.

MR. BARNHORN: It is a little different, then. I want to make sure that packing house or similar level of grading, which I think is relevant here.

MS. OLIVER: Do we need more clarification? Does the committee need more clarification on this?

DR. GROVES: This is Mike Groves.

On one and two up there, are we talking about, one, that it is the 5-log reduction that begins before cleaning and culling, like cleaning and culling, and two, after the brief wash and cull, and two is not meaning that it is after sanitization and brush washing. Is that correct?

DR. BUCHANAN: This is Bob Buchanan from FDA.

For point of clarification, number one would be that you would start the 5D as the juicer received the oranges, okay?

Number two would be you would start counting the 5D from the moment you start the sanitation, brush-wash cycle, et cetera. The difference between one and two would be that you do not count the brief wash, brief cull that is in between steps one and two. That would be the difference.

MS. OLIVER: Mike?

DR. JAHNCKE: Mike Jahncke.

I have a quick question. If we are going to be doing this, we have got citrus going through the packing house, and it is not only getting a brief wash. It is getting sanitized, brushed, and washed, versus material that is coming directly from the grove to the juicer. I do not think we can apply the point of where we are going to start the 5D. They are two different processes. They are not equivalent.

MS. OLIVER: Bob, do you have any response?

DR. BUCHANAN: I guess I am a little bit--

MS. OLIVER: John Kvenberg does.

DR. KVENBERG: Yes, let me try again. This is John Kvenberg.

I think what we are trying to say is the process, and maybe "culling" is an inappropriate word. We are really talking about acceptance of fruit that is going to be processed by the juicer on receipt or removal from cold storage, either within its own facility or from a packing house. So what we are saying is acceptable fruit.

The two points may or may not include a brief wash. I do not know, but basically the sanitation and brush-washing process in the control of the processor is where the count should begin.

It may not be total receipt, but there has to be a grading, if not a culling, given the last point of the speaker that the thing is coming in crated. It has to go through something, so you have an initial starting point.

The point we were trying to make was gross cull. It did not count in the 5D process.

Thank you.

MS. OLIVER: Dr. Troxell?

DR. TROXELL: Thank you. This is Terry Troxell.

What Bob said, I believe, was we are talking about sound fruit. In my mind, sound fruit involves fruit that is not damaged and it is fruit that is clean. So that is what we are talking about. The difference would be that you would make sure that whether it came from the grove or the packing house that had the cold storage, that you had rechecked that fruit to ensure it is clean and sound before you put it in the process, and then you have your double-check.

For example, yes, it is supposed to be tree-picked, but you would have a verification under your control that everything you are putting into the process is sound; that is, cleaned and culled.

MS. OLIVER: Dane?

DR. BERNARD: Thank you. Dane Bernard.

I agree with what Terry said. That was my concept, that whatever goes to step two there is relatively clean, sound, choice, whatever you want to call it. Then you push down the button and you say, "Okay, start." That is where we start counting.

In relation to the other questions that were on our list, though, there were a number of us who said that all that ought to be done under a roof, and I think that is where we started with Bob's red line.

We had an intervention from a juicer who buys packing-house fruit which has already gone through a lot of that. My intent would be do it again because we were concerned about separating of steps in time and space. I want to make clear that that was my intent there and see if that is the sense of the committee.

Thank you.

MS. OLIVER: Bob?

DR. BUCHANAN: Dane, that was my assumption in looking at that diagram that was provided with us.

The juicer is a location, and it was upon receipt at that location. If you move to another location, based on our comments and what I thought was pretty much the opinion of the committee, you would have to start that process over again.

MS. OLIVER: He is asking you a question, Bob. Leon is asking a question.

DR. RUSSELL: Leon Russell, Texas A&M.

You mean start the 5-log reduction again if you go to another place, transport?

DR. BUCHANAN: That was my understanding based on the answers to Question II-B was that if you were transporting fruit or juice in between locations that people

seemed to have a great deal of concern about being able to achieve part of a 5D kill at one location, then the rest at a second location.

DR. RUSSELL: Leon Russell again.

Should we not use a different criteria? Could you meet a 5-log reduction, refrigerated, aseptic, if you want to call it that?

DR. BUCHANAN: I am not sure of your point.

DR. RUSSELL: You are going to start the 5D reduction again once you go to a new plant, right?

DR. BUCHANAN: Right.

DR. RUSSELL: Is that possible or feasible?

DR. BUCHANAN: 5D, I think there is some confusion here because I have seen this. 5D represents the degree of processing that would be needed to achieve a certain level of reduction, regardless of whether the organism is there or not. It is a risk-reduction approach.

You can have 103 organisms and give them a 5D. What that means is you are now down to a probability of less than 1 in 100 that there is a surviving organism.

We heard earlier commentary about shelf-stable juice receives a 50,000D. There is no way, since 1013 is solid bacteria, in the world you could have 1050,000 in any kind of realistic 1-ml volume, but you can still get that kind of a treatment just on the basis of continually first-order kinetics in terms of an activation theory.

MS. OLIVER: Bruce?

DR. TOMPKIN: We are on two points now. Have we reached a consensus as to where to draw the line first and begin the 5D reduction for fruit entering a juicing operation?

MS. OLIVER: Have we reached a consensus? No, they did not reach a consensus on the other. I am saying you need a consensus on where to ask the question from. This is a different thing.

I will tell you what, I am going to ask the question, and if everybody would just describe from whence they are saying the 5-log should be in terms of cleaning and culling and what you mean by it as opposed to understanding and answer the question in that vein, would that help?

MS. OLIVER: Bruce?

DR. TOMPKIN: It is my understanding that we are at a point where the 5D reduction begins after the initial culling upon receipt of the fruit into the operation.

DR. LONG: Earl Long, CDC.

That is my understanding, too.

DR. BERNARD: Dane Bernard.

That is my understanding.

MR. SEWARD: Skip Seward.

I agree with that.

DR. NEILL: Peggy Neill.

I agree with that. I think I might suggest inserting the words "culling," borrowing from Terry Troxell, "the culling step to identify sound fruit."

DR. ACHESON: David Acheson.

I agree with that, beginning with clean fruit.

DR. KVENBERG: This is John Kvenberg.

I agree also with the second intervention, sound fruit.

DR. DOORES: Stephanie Doores.

I agree with that.

DR. DOYLE: This is Mike Doyle.
I also agree.
DR. ENGELJOHN: Dan Englejohn.
I agree.
DR. LIANG: Art Liang.
I agree.
LTC SEVERIN: Scott Severin.
I agree.
MR. EKLUND: Mel Eklund.
I agree.
DR. ANDERS: Jim Anders.
I agree.
DR. MORALES: Roberta Morales.
I agree.
DR. SWAMINATHAN: Bala Swaminathan.
I agree.
DR. BUCHANAN: Bob Buchanan.
I agree.
DR. SPERBER: Bill Sperber.
I agree only for citrus.
[Laughter.]
DR. DICKSON: Jim Dickson.
I agree as well.
DR. GROVES: Mike Groves.
I agree.
DR. KOBAYASHI: John Kobayashi.
I agree.
DR. JAHNCKE: Mike Jahncke.
I agree.
DR. RUSSELL: Leon Russell.
I would not dare not agree. I agree.
[Laughter.]
MS. OLIVER: Thank you, everyone.

Now I have another question that I had started with before, and that had dealt with microbiological testing. The testing was brought up by Mike Doyle, by Stephanie, by John Kvenberg, by Dane, and I do not recall who on this side, but also someone on this side. I have a question, as I heard the testing a little bit differently from each of you. I am wondering what you are meaning by testing. If I could have a clarification or possible discussion on that.

Dane, could I begin with you?

DR. BERNARD: Thank you. Dane Bernard.

My intervention earlier referred to finished product testing. We had a very, I think, convincing presentation of information from a compilation of the four processors who are doing microbiological testing.

There was also a lot of discussion about the methodologies used, how they have changed. All of that aside, 17,000 negatives is an impressive data set, and I think they are to be complimented for that.

However, I think that what we need to do is as a committee give some expression as to the value of finished product testing with fresh citrus products, what we think might be appropriate as finished product testing, and on what frequency. There are those on the committee who are much more expert than I who might have some opinions on that, but I would see some type of testing on a lot basis and an occasional more in-depth testing for specific pathogens.

One of the criteria that we might want to think about is how one would react to a positive finding for, say, E. coli or fecal coliforms, whatever the preferred organism might happen to be. E. coli would provide, I think, a good tracking mechanism as to how you are doing in your process. Since sanitation of equipment, brushes, maintenance of equipment appears to be a very important factor, I think a microbiological verification on finished product is a tool that is probably something that should be used.

I will just open the conversation with that and let others jump in.

MS. OLIVER: Bruce?

DR. TOMPKIN: This is Bruce Tompkin.

I think that the ongoing practice of testing for E. coli as a means to assess the control of the process has considerable value, and that should be continued. The data should be plotted, as some are now doing.

When it gets beyond that, to impose a lot acceptance sampling plan on product prior to shipment, I think it is unnecessary based on the history or at least based on the data of those establishments that currently apply to Florida principles of best practice, let's call them. However, it would be useful in the event of a questionable lot to have a sampling plan that would be applicable.

And I know that in the past FDA and others have established a microbiological criterion or sampling plan that provides guidance to industry as to how to design and control its processes. So, for example, it could be 60 samples in the case of that--no, excuse me--30 samples--30, 60 samples based on 25 individual analytical units, and those could be analyzed as composites or not, depending on how that data shakes out. But that would not be done on a routine basis.

MS. OLIVER: John?

DR. KVENBERG: Thank you. John Kvenberg.

I was speaking in the term of sampling in the context of HACCP verification. I think the sampling frequency will depend on the confidence of the system that has been validated, and should be frequent until confidence is gained and then moved apart. I am not talking necessarily about lot by lot verification. Speaking to what to be tested for, I think our history would indicate that Salmonella may be better than E. coli for this purpose.

MS. OLIVER: Mike Doyle.

MR. DOYLE: Mike Doyle, University of Georgia.

And I saw what FDA did with sprouts, and has set up a end-product testing for sprouts, and I guess I don't see the fresh juice situation to be too much different from that, and if we're going to establish end-product testing as what I would call the equivalent of a critical control point, then I would concur with what Dane had to say, although John has some good points too. If it's found that there's a strong history of product being microbiologically safe, then there just needs to be certain tests done on a verification basis with time. But I think both E. coli and Salmonella have a place in this--not E. coli 0157 necessarily, but E. coli as an indicator organism.

MS. OLIVER: Okay, Scott.

DR. SEVERIN: Yes. Scott Severin, DOD.

My concept was final product testing, focusing

primarily on Salmonella and E. coli, more a verification of system processes control, along the lines of what Dane was describing.

MS. OLIVER: Thank you. Bob?

MR. BUCHANAN: Bob Buchanan, FDA.

My inclination that we're primarily looking here as a microbiological testing as a verification for a HACCP program. There are several different sampling techniques that can be used in conjunction with that. It can be tailored to the defect rate that you actually are experiencing or that you have concerns about. It can also be coupled--if positives come up for whatever organism you select to be monitoring for organisms.

So, for example, you are dealing with E. coli, generic E. coli as an indicator organism of process control, and you begin to have positives on that, or positives beyond some baseline. You then can move into a more rigorous lot acceptance criteria as part of your HACCP plan for specific pathogens such as Salmonella or any of the other organisms of concern.

I think particularly considering that we have a process for which we do not have a great deal of scientific data, and that we had some discussions about potential concerns, including microbiological testing as part of the HACCP verification program, is a wise precaution.

MS. OLIVER: Bill?

DR. SPERBER: Bill Sperber, Cargill.

I think two types of microbiological testing would be required to have an effective program. Pathogen testing would be useful for verifying the HACCP plan. This is something that would be done irregularly or maybe on a weekly basis, something done for a process that's under control.

But the processor is going to have to do some other microbiological testing to know that its process is under control, and do this testing on a regular basis, perhaps daily, and pathogens are not useful for that kind of testing, simply because they're so infrequent. So there has to be some other type of indicator organism, perhaps it's coliforms, or in the case of juice, yeast might be a better example because it's more likely to be there if something is not done properly. So there should be some kind of an indicator organism that's used to verify process control.

MS. OLIVER: Thank you. Jim?

DR. DICKSON: Jim Dickson, Iowa State.

I guess I'd like to support what's been said up to this point. The only thing I'd like to add is that when we talk about testing for specific pathogens, particularly in a case where we're talking an incidence of what, 3 to 4 per 100 mls., that that doesn't lend itself to setting up a statistically valid sampling that can be operated on a daily or a weekly basis.

My concern is that as a food industry, we do an awful lot of microbiological testing, but when you look at the sampling plans behind it, basically most of that data doesn't mean very much, because the plans are not statistically valid.

I agree with Bill here that there is a role for some kind of an indicator organism for process control, but if we're going to do specific pathogen testing, a whole series of Salmonella negatives from a sampling plan that is

not statistically valid really doesn't mean very much.

MS. OLIVER: Thank you. Mike?

DR. JAHNCKE: No, I'm sorry. Didn't know my flag was up. Thank you.

MS. OLIVER: All right. Dane?

DR. BERNARD: Thank you. Dane Bernard.

Let me make it clear again we're talking about fresh citrus juice in this particular context.

MS. OLIVER: Right, okay, thank you.

Stephanie.

DR. DOORES: Stephanie Doores, Penn State.

I would like to address--and maybe I should wait until this issue is finished--about the methods used to ascertain the coliforms, and it's related to this, but it may be different from where other people are coming from, so I think I'll hold on that until we finish this particular discussion right now.

MS. OLIVER: Okay. Mike, you have something now?

DR. JAHNCKE: I do have a question now, thank you.

Mike Jahncke, Virginia Tech.

I think it would also be helpful, in the Florida guidance document, they do have some recommendations as far as testing and lots and sample sizes. We still haven't gotten a good explanation of how that's being followed and/or the logic behind how that was even designed, and why that type of a program was put in place. You know, obviously, a lot of thought went into it, probably by the industry and also by people in the state of Florida, and I think it would be helpful to get some of that background too at some point.

MS. OLIVER: Bruce?

DR. TOMPKIN: Bruce Tompkin.

It's not clear what the definition of a lot is, and that has to be addressed in the establishment of a sampling plan.

MS. OLIVER: John?

DR. KVENBERG: It's current industry practice, as I understand it, to track total plate count--

MS. OLIVER: Please identify yourself.

DR. KVENBERG: John Kvenberg, Food and Drug Administration, slow learner.

[Laughter.]

DR. KVENBERG: It is my observation that total plate counts are currently used, and it may go to the idea to determine if your process is in control or moving out of control. I offer this only as an information that I know. I don't know about the suitability of that as an indicator.

MS. OLIVER: Bill?

DR. SPERBER: Bill Sperber, Cargill.

I agree total plate counts might be a good indicator. I mentioned yeast before. I think total plate counts would be better than yeast.

Also, another possibility better than yeast would be a lactic acid bacteria.

MS. OLIVER: Thank you. Stephanie, could I come back to you about your methods, your question?

DR. DOORES: Stephanie Doores, Penn State.

If we're talking about total plate counts or coliforms or fecal coliforms or E. coli as indicators, I have several concerns with the procedures that are used to assess these numbers. If one is doing a total plate count

by the traditional method, i.e., a standard plate count, generally there is a dilution effect by using the agar in the plate. Now, this particular product is going to have a low pH, and it may have other naturally occurring inhibitory properties, probably dependent upon how much oil is in the product, and this may vary from manufacturer to manufacturer.

If one uses something like a petri film, which is an excellent method, but you have a similar amount that's added for your sample size, but it does not go through a dilution effect on that petri film plate, and if I'm assuming--and this becomes more problematic with the coliforms, that you have a low number there. You may have some inhibitors coming over that interfere with the test, i.e., you're not going to get the organism showing up on something like a petri film where you may have it in an agar plating method or most probable number method. So it might lead you to think that you're having or achieving the reduction of organisms, but it's an artifact of the method used.

So what I would like to see--and maybe ARS has this, these data--is whether these testing methods have been used specifically with orange juice as a sample, perhaps using some coliforms that have been isolated from orange samples too that are indigenous to that particular product, or that they've looked at the carryover of orange juice into these sampling procedures to see whether it has an effect.

MS. OLIVER: Thank you. Does anybody else have any comments before I turn it over to USDA to describe what we'll be doing tomorrow and then we adjourn for the day, any specific comments?

DR. BERNARD: Dane Bernard. Considering the lateness of the hour, maybe we shouldn't even venture into this discussion, but I do have a good deal of concern about discussions regarding what we've referred to as HACCP or GMPs or whatever.

A lot of the success of putting a fresh juice that presents a minimal risk of pathogens in it appears, as a result of my education over the last day and three-quarters, as to how it is done, and we've spoken a lot to that in our recommendations.

However, saying HACCP does not trigger automatically high pressure washers and specific kinds of brushes that are incorporated into the Florida protocol, and that bothers me a little bit, because I think that if we look at past problems--and it's been said before by many presenters, they have not been related--and I think we've all come to that conclusion--to internal contamination in the fruit, but to other failures, and I don't that we've addressed as a Committee the entire scope of the juice problems that we've had, and I know we don't have time to solve that today, but we're walking out of here, as far as I'm concerned, without really addressing some of the nuts and bolts issues of the problems that have arisen, and what we mean when we say HACCP, and how do we trigger the kind of system that is more or less embodied in the Florida plan and make sure that the California plan and the Texas operators and the Arizona operators use acceptable protocol. That was my concern.

MS. OLIVER: Thank you, Bruce.

DR. TOMPKIN: Bruce Tompkin. The Florida best

practices document was written in '95, '96, and the National Advisory Committee issued its HACCP update in '97. I think it would be appropriate for the--whatever comes out of this process, that it should be done with the current '97 advisory committee recommendations relative to HACCP and prerequisite programs as a guide.

MS. OLIVER: Thank you. Bob?

DR. BUCHANAN: Bob Buchanan, FDA.

I'd also like to echo Bruce's comments. A good HACCP program is one that not only is implemented and shows up on paper, but it's also one that is capable of catching its mistakes. And any program that is initiated and is not adequately catching its mistakes, having an appropriate contingency plan on what to do when there are out-of-spec operations is an incomplete HACCP plan, and so I think there has to be a lot of attention paid to going back to the sound principles that we've helped develop here in this Committee in insuring that they are appropriately applied, which includes a great deal of contingency planning on what can go wrong and what will go wrong, and insuring in your HACCP plan that you're addressing those things, because while I know that there is some sensitivity about this term, HACCP takes into account Murphy's Law and does a lot of forward planning, contingency planning on what should be done and what can be done to make sure that we catch those problems, not only in hazard analysis, but also in implementation.

MS. OLIVER: Thank you. Jim?

DR. ANDERS: Jim Anders, North Dakota Health.

Yes, I agree. I think that I'd personally like to see a mandatory standardized HACCP plan, because everybody says they have a HACCP plan and everybody's got a different HACCP plan. In this particular case, we're talking about unpasteurized juice. It seems to me that there could be a very clear standardized HACCP plan that could be used in all the states.

Secondly, I think that you have to validate that with some testing, and there has to be some validated testing.

And thirdly, because it's unpasteurized, it would seem to me that there needs to be some end testing, whether that's every lot or whatever that is, that it needs to be some end testing done to at least give some semblance of safety to the product since it's unpasteurized.

So I guess--and we even ran across a couple of other things here, and that is on the use of fresh juice. Something that is bottled for 17 days is hardly in the same category as something that is--they prepared the juice this morning and you're going to use it today. So I guess--and it seems to me that they're using the fresh label for both of those concepts.

So it seems to me we have a whole series of things here that's not just--we haven't answered all these problems today.

MS. OLIVER: Thank you. Seeing no more comments, I'd like to--before I turn it over to USDA--to thank the Committee for bearing with us for the full two days. They've been two long days, and thank you very much for the advice that you've given us today.

And I also would like to apologize for not having a better clarification on what we meant in our question on culling and cleaning, because it did take us a while to

flesh that out this afternoon, and I apologize.

With that, I'd like to just let you know that you have background materials that have been passed out from USDA on FSIS on tomorrow's session, and turn it over to Dan Engeljohn to give a little brief intro into that.

DR. ENGELJOHN: Thank you, Janice.

Dan Engeljohn with USDA.

I just want to remind you all that you do have a packet which contains the handouts that are going to be used tomorrow in the description of the FSIS risk assessment for E. coli 0157:H7 in ground beef.

The modelers will be presenting their sessions on production, slaughter, preparation and dose response.

In addition, we've invited some subject matter experts to participate. We'll be seeking your input and your guidance and comments on the risk assessment as we present it, and we'll be taking comments on that tomorrow, as well as for a few weeks after the presentation tomorrow. So we'll talk more about that and we'll begin at 8:00 o'clock.

MS. OLIVER: Yes. Tomorrow's session begins at 8:00. And thank you all very much, and enjoy your evening.

(Whereupon, the proceedings were adjourned at 4:21 p.m.)

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